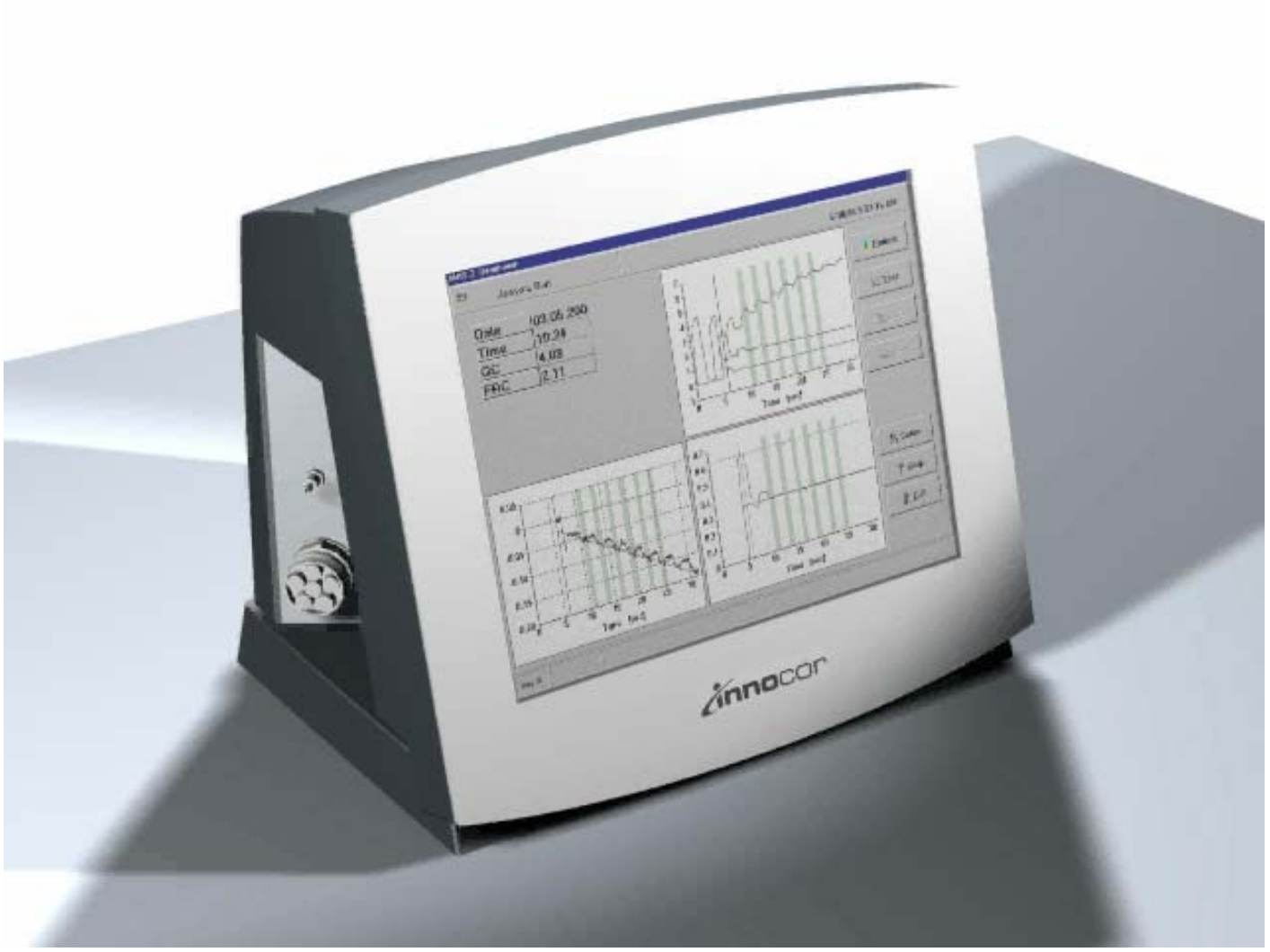
Innocor™

SERVICE MANUAL



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1 INTRODUCTION AND APPLICABILITY OF THIS MANUAL

1.1 APPLICABILITY OF THIS MANUAL

This service manual provides information required to maintain and repair all models of the Innocor. This manual is applicable for the current production revision.

Section 1:
Section 1 gives an introduction to the Innocor. Differences between models are summarised in section 1.3. Section 1.4 lists history of this document. Section 1.5 lists the hardware changes made to the Innocor and section 1.6 the software changes.

Section 2 gives a general description of the Innocor and its sub-modules.

Section 3 gives a more detailed description of the Innocor.

Section 4 describes the maintenance of the Innocor.

Section 5 gives a troubleshooting for the Innocor.

Section 6 lists the error / warning messages given by Innocor.

Section 7 describes the disassembly and reassembly of the Innocor.

In the following all functions and options of **Innocor** are described. Some of the functions described or shown may not be available on the device you are using.

1.2 INTRODUCTION TO INNOCOR

1.2.1 INTENDED USE

Innocor is a compact point-of-care device intended to be used for non-invasive measurement of cardiac output and related cardiopulmonary parameters. Cardiac output (CO) is defined as the volume of blood pumped by the heart per unit of time (blood flow in litre per minute). The measurement is non-invasive (i.e. does not necessitate catheterisation or any other penetration through a body orifice or the body surface) in that it is based on a pulmonary gas exchange method called inert gas rebreathing (IGR).

The operating principle of **Innocor** is to let the patient breathe minute quantities of a blood soluble and an insoluble gas in a closed breathing assembly for a short period. The blood flowing through the lungs (effective pulmonary blood flow, PBF) absorbs the blood soluble gas and therefore the disappearance rate is proportional to the blood flow. Other factors affecting the distribution of the blood soluble gas are accounted for by also measuring the blood insoluble gas.

The spontaneously breathing patient puts on a nose clip and breathes into a respiratory valve via a mouthpiece and bacterial filter. At the end of expiration the valve is activated so that the patient will breathe in and out (rebreathe) from a rubber bag for a period of 10-20 seconds. The patient is asked to empty the bag during each inspiration and breathe with a slightly increased respiration rate. After this period the patient is switched back to ambient air and the test is terminated. The bag is prefilled with an oxygen (O_2) enriched mixture containing two foreign gases; typically 0.5% nitrous oxide (N_2O) and 0.1% sulphur hexafluoride (SF_6). These gases and CO_2 are measured continuously and simultaneously at the mouthpiece by a photoacoustic gas analyser inside **Innocor**.

N_2O is soluble in blood and is therefore absorbed during the blood's passage of the lungs at a rate, which is proportional to the blood flow. So, the higher the cardiac output the higher the disappearance rate (slope of measured gas curve). SF_6 is insoluble in blood and therefore stays in the gas phase and is used to determine the lung volume from which the soluble gas is removed.

The rebreathing test can be performed as a single test at rest or at a given exercise level using e.g. a bicycle ergometer or a treadmill in a stand-alone configuration. Alternatively it can be performed as a part of an exercise protocol where the rebreathing manoeuvres are done at pre-programmed intervals/workloads.

By using a pulse oximeter the heart rate (HR) can be measured during the test and used to derive the stroke volume (SV) etc. The arterial oxygen saturation (SpO_2) indicates whether the oxygenation is normal and thus if there is a significant intrapulmonary shunt ($SpO_2 < 95\%$).

An oscillometric non-invasive blood pressure (BP) measuring system is also included as an option. It is designed to take blood pressure measurements including systolic (SYS), diastolic (DIA) and mean arterial pressures (MAP). By combining CO and MAP the systemic vascular resistance (SVR) can be determined.

The BBB (Breath-by-Breath) option provides measurements of gas exchange parameters including oxygen uptake, carbon dioxide excretion, ventilation and end-tidal concentrations plus a number of derived parameters. These parameters are determined by simultaneous measurements of the respiratory flow and gas concentrations when breathing ambient air. The respiratory flow is measured by means of a differential pressure type flowmeter (pneumotachometer) placed between the respiratory valve unit and the patient. The gas exchange calculations are carried out online for each breath between the rebreathing tests. This gives the opportunity to perform an incremental exercise test on a bicycle ergometer or treadmill and measure the progress of cardiac function, pulmonary function and gas exchange at the same time.

Innocor runs under the Windows XP Embedded operating system on an integrated single-board computer. However, knowledge of Windows is not required to operate the device. The device is operated via a simple touch screen interface. Simply touch/press the buttons on the screen to invoke the desired functions. There is no significant warm-up time required for use of **Innocor**.

1.2.2 INTENDED APPLICATIONS AND PATIENT POPULATION

Innocor can be used in a variety of medical fields where knowledge of cardiac output and gas exchange is important, e.g. cardiac exercise stress testing, heart failure, cardiac surgery, hypertension, pulmonary hypertension, haemodialysis and pacemaker programming. It can be used both in rest and exercise e.g. with patients who have no symptoms in rest or light exercise. The method involves no risk or pain to the patient. The only requirement is that the patient is capable of understanding the instructions from the operator and performing the manoeuvre well.

1.2.3 INTENDED OPERATORS AND ENVIRONMENT

Unspecialised nurses and paramedics in all parts of the health care system can use **Innocor**. However, qualified medical personnel should always supervise the user.

1.3 INNOCOR MODELS

Innocor is produced in different models. An overview of the models is given in the table below.

Model	Oxygen sensor	Blood pressure sensor	Breath-by-Breath
INN0050			
INN0100	√		
INN0200		√	
INN0300	√	√	
INN0400	√		√
INN0500	√	√	√

1.4 SUMMARY OF REVISION CHANGES

A/1	Sept. 2003	First release
A/2	Nov. 2003	Spare parts section added
A/3	Feb. 2004	Section “Inert Gas Rebreathing Method” updated
A/4	May 2004	“Software User Manual” & “Inert Gas Rebreathing Method” made as separates documents
A/5	Sep. 2004	Spare parts list modified
A/6	Mar. 2005	Minor updates
A/7	Jan. 2007	Breath-by-Breath option included Calibration procedures updated Typical rebreathing curves included

1.5 HARDWARE UPDATES

Feb. 2002	Updated with blood pressure measuring function (NIBP)
Feb. 2002	I/F board updated
Nov. 2003	New gas supply design incl. relief valve New flow pump attenuator New silicone 6 tube
Apr. 2004	New Innocor RVU (replaces the Hans Rudolph valve)
May 2005	Updated with Breath-by-Breath

1.6 SOFTWARE CHANGES

5.07	01.11.06	Script Support for updating system files (*.ini)
5.06	22.06.06	Bug in controlling a manual treadmill protocol corrected
5.05	22.05.06	Faster preparation of rebreathing bag
		Service interval reminder
		Native country
5.04	02.05.06	Updates for the US market
		Breath-by-Breath updates
		New Export facilities
		Support for HR & BP from exercise devices
		Faster preparation of rebreathing bag
5.03	01.12.05	Support for variable flow zero calibration interval
5.02	01.09.05	Printout to Microsoft EMF files (Enhanced Metafile)
5.01	12.08.05	Support for bolus concentration up to 50%
5.00	02.06.05	Breath-by-Breath gas exchange calculation
		Improved regression lines in Data View
		New symbols
		Improved exercise protocol
		Scandisk in case of unauthorized power down
4.01	17.12.04	Bug in O2-adjust corrected
4.00	23.09.04	Exercise protocol
		Calculation of SVRI changed
		Calculation of SVO2 changed
		New handling of calculation warnings
		Standby of gas supply
		Improved bottle pressure handling
		Improved script handling
		Improved service menu
		Improved handling of databases in case of off-nominal shut down
3.02	19.04.04	New trend function with support for display of parameters in tables and XY-plots
		Support for manual entering of HR, SpO_2, Load, Speed, Slope
		Support for User defined parameters
		Support for calculated parameters based on database values
		Support for rebreathing bag volume down to 0.5 litre
		Improved on-line detection to avoid bag opening in the shift from inspiration to expiration.
		A test is always saved - also in case of errors - in order to display the data to determine the reason for the error.
		Support for deleting a gas cylinder from the Gas Cylinder list
		New exit / close down of Innocor
		New database format (3.02 will automatically convert existing format)
		Innocor software can run as an offline viewer on a memory key
		New help pages
3.01	28.10.03	Support for setting of default printers
3.00	19.09.03	Innocor software running under Windows XP embedded
2.02	12.09.03	Estimation of bag volume to 40% of VC
		Automatic stop after 3 breaths after good mixing
		Support for beep during rebreathing
		Support for manual entering of blood pressure
		New parameters: Vo2/kg & A-V O2 diff.
		Support for script execution (Copy, Move, Delete etc.)
2.01	13.03.03	Gas bottle identification implemented
2.00	26.11.02	Support for different languages implemented

2 GENERAL DESCRIPTION

2.1 OPERATIONAL SPECIFICATION

Parameters

CO	Cardiac output
CI	Cardiac index *
SV	Stroke volume
SI	Stroke index *
PBF	Pulmonary blood flow
VL	Lung volume (or FRC, Functional Residual Capacity)
HR	Heart rate
SpO2	Arterial oxygen saturation
SvO2	Mixed venous oxygen saturation **
A-V O2 diff	Arterial – mixed venous oxygen saturation **
VO2	Oxygen uptake **
VO2/kg	Oxygen uptake pr kg **
Shunt	Intrapulmonary shunt fraction **
SYS	Systolic blood pressure **
DIA	Diastolic blood pressure **
MAP	Mean arterial blood pressure **
SVR	Systemic vascular resistance **
SVRI	Systemic vascular resistance index **
Hb	Haemoglobin concentration *
BSA	Body surface area *

Breath-by-Breath gas exchange parameters:

VO2	Oxygen uptake
VO2/kg	Oxygen uptake pr kg
VCO2	Carbon dioxide excretion
R	Respiratory exchange ratio
Ve	Expiratory minute ventilation
Va	Alveolar ventilation
Vd	Anatomical dead space
Vt	Tidal volume
Resp.Freq.	Respiratory rate
FO2et	End-tidal concentration of oxygen
FCO2et	End-tidal concentration of carbon dioxide
Ve/VO2	Expiratory quotient / ventilatory equivalent for oxygen
Ve/VCO2	Expiratory quotient / ventilatory equivalent for carbon dioxide
HR	Heart rate
SpO2	Arterial oxygen saturation
Load	Exercise level on bicycle ergometer
Speed	Running speed on treadmill or Pedal speed on bicycle ergometer
Slope	Slope on treadmill

The following parameters can be calculated after an incremental exercise test:

AT	Anaerobic threshold (measured by V-slope***)
RC	Respiratory compensation (measured by V-slope***)

Rest and max values of all Breath-by-Breath parameters.

* *Requires manual input.*
** *Requires optional sensors.*
*** *Beaver WL, Wassermann K, Whipp BJ (1986) "A new method for detecting anaerobic threshold by gas exchange" J Appl Physiol 60:2020-2027*

Gas analyser

Principle:..... Photo acoustic Spectroscopy
Components and ranges:..... N_2O 0-2.5%, SF_6 0-0.5%, CO_2 0-10%
Accuracy:..... ± 1% relative
Signal-to-noise ratio: ..... > 1000 @ 1% N_2O
..... > 1000 @ 0.2% SF_6
..... > 400 @ 5% CO_2
Sampling frequency:..... 100 Hz
Sample flow rate:..... 120 ml/min
Rise time (10-90%):..... < 250 ms
Calibration check interval: ..... 12 months

Oxygen sensor

Principle:..... Laser diode absorption spectroscopy
Measuring range: 5-100%
Accuracy:..... ± 1% relative
Signal-to-noise ratio: ..... > 500 @ 21% O_2
Sampling frequency:..... 100 Hz
Sampling flow rate:..... 120 ml/min
Rise time (10-90%):..... < 250 ms
Calibration check interval (2-point):..... 12 months
Calibration (check interval) (1-point): ..... 1 month

Flowmeter

Principle: ..... Differential pressure
Measuring range: ..... ±15 l/s
Accuracy: ..... ±2% relative or ±20 ml/s
Resolution: ..... 1 ml/s
Sampling frequency: ..... 100 Hz
Lowpass filter: ..... 18 Hz
Offset calibration interval: ..... auto
Gain calibration interval: ..... 1 day

Pulse oximeter

Oxygen saturation range: ..... 0 to 100%
Pulse Rate Range: ..... 18 to 300 pulses per minute
Measurement Wavelengths: Red - 660 nm Infrared - 910 nm
S_pO_2 accuracy (70 - 100%) (± 1 SD*): ± 2 digits
S_pO_2 accuracy (below 70%): Not specified
Heart Rate accuracy (No motion, 18-300 BPM): ± 3 digits
Heart Rate accuracy (Motion, 40-240 BPM): ± 5 digits
Heart Rate accuracy (Low perfusion, 40-240 BPM): ± 3 digits
Patient Isolation: Meets 60601-1 Dielectric withstand
Leakage Current: Not applicable

The pulse oximeter is designed to use Nonin sensors only.

*SD (Standard Deviation) is a statistical measure:
Up to 32% of the readings may fall outside these limits.

Non-invasive Blood Pressure (NIBP)

Method of measurement: ..... Oscillometric
..... Diastolic values correspond to Phase 5 Korotkoff sounds
Blood pressure range:
- Systolic: ..... 40 mmHg to 260 mmHg
- Diastolic: ..... 20 mmHg to 200 mmHg
Heart rate range: ..... 40 BPM to 200 BPM (Beats Per Minute)
Transducer accuracy: ..... ± 3 mmHg between 0 mmHg and 300 mmHg

2.2 TECHNICAL SPECIFICATION

Mechanical

Size: ..... 32 x 26 x 24 cm
Weight: ..... 8-9 kg (depending on options)

Electrical

Power supply: ..... 220-240 V ± 10%, 50/60 Hz
..... 100-120 V ± 10%, 50/60 Hz
Power consumption: ..... 45 W nom., 100 W max.
Fuse requirements: ..... 2 x 1A T/250V
Protection: ..... Class I type BF according to EN-60601-1

Environmental

Operating temperature: ..... 10 – 40 °C
Operating pressure: ..... 525 – 800 mmHg
Operating humidity: ..... 10 - 90 % RH, non-condensing @ 30 °C
Warm-up time: ..... 2 minutes
Storage temperature: ..... -20 to +50º C
Storage humidity: ..... 0 to 90 % (not condensed)
Dust and direct sunlight to be avoided.

Display

Type: ..... Colour TFT LCD display
Size: ..... 12.1"
Resolution: ..... SVGA (800x600 pixels)

Touch screen:..... High-resolution resistive type

Integrated computer

Processor: ..... 586 class 300 MHz Pentium MMX
Hard disk: ..... 10 or 20 GB
Operating system: ..... Windows XP embedded

Electrical interfaces

Networking: ..... 10/100 Mbps Ethernet
PC interfaces:..... 2 x Universal Serial Bus (USB 1.1)

CAUTION:
The electrical interfaces on the data interface panel (USB and Network) shall not be used under normal clinical conditions within the patient zone but only during service and occasionally for data exchange.

Peripheral equipment connected to these interfaces must be certified according to the respective European standards (e.g. EN 60950 for data processing equipment and EN 60601-1 for medical equipment).

Furthermore, all configurations shall comply with the system standard EN 60601-1-1. Everybody who connects additional equipment to the signal input part configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard EN 60601-1-1.

LAN interfaces

Speed:.....10 / 100 Mbps
Type: ..... Ethernet - TCP/IP
IP address (default):.....10.0.0.x
Workgroup (default):..... INNO_WRKGRP
Computer name (default): .....*"Innocor serial no"*
Logon from remote computer (access to c:\innocor\databases, c:\innocor\rawdata & c:\innocor\export):
User access:
User Name: ..... InnoUser
Password:..... innopass
Super user access (access to all):
User Name: ..... InnoSuper
Password:..... superpass

Exercise I/F

Elmed EGT 1000 ergometer
Ergoline VarioBike 550 ergometer
Ergoline 800&900 ergometers
Ergoline ergoselect ergometers
Lode Examiner ergometer
Lode Excalibur ergometer
Monark 839 ergometer
HP Cosmos Series treadmill

Rebreathing valve

Pneumatic operation
Disposable bacterial/viral filter for single patient use
Hans Rudolph Valve (8200 series):
Bag dead space ..... 13 ml
Instrument dead space @ rebreathing (excl. bag dead space) ..... 102 ml
Instrument dead space @ prior to rebreathing ..... 110 ml

Innovision Respiratory Valve without Breath-by-Breath
Bag dead space ..... 13 ml
Instrument dead space @ rebreathing (excl. bag dead space & filter) .... 87 ml
Instrument dead space @ prior to rebreathing (excl. filter) ..... 67 ml

Innovision Respiratory Valve with Breath-by-Breath
Bag dead space ..... 13 ml
Instrument dead space @ rebreathing (excl. bag dead space & filter) .... 95 ml
Instrument dead space @ prior to rebreathing (excl. filter) ..... 75 ml
Dead space of BBB port of RVU ..... 40 ml

Filter dead space, PALL (52 ml) ..... +41 ml
Flexible tube ..... +56 ml

Gas supply

Gas composition: 5% N2O, 1% SF6, 94% O2
Cylinder capacity: ..... 18 liters (0.15 l @ 124 bar)
Typical number of tests using automatic dilution with air: 75

2.3 CERTIFICATION / SAFETY STANDARDS

93/42/EEC ..... Medical Device Directive
EN 60601-1 ..... General Requirements for Safety
EN 60601-1-1 ..... Safety Requirements for Medical Electrical Systems
EN 60601-1-2 ..... Electromagnetic compatibility
EN 865: 1997 ..... Pulse oximeters - Particular requirements
EN 1060-1: 1995 ..... Non-invasive sphygmomanometers - Part 1: General requirements
EN 1060-3: 1997 ..... Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electromechanical blood pressure measuring systems

2.4 GENERAL BLOCK DIAGRAM

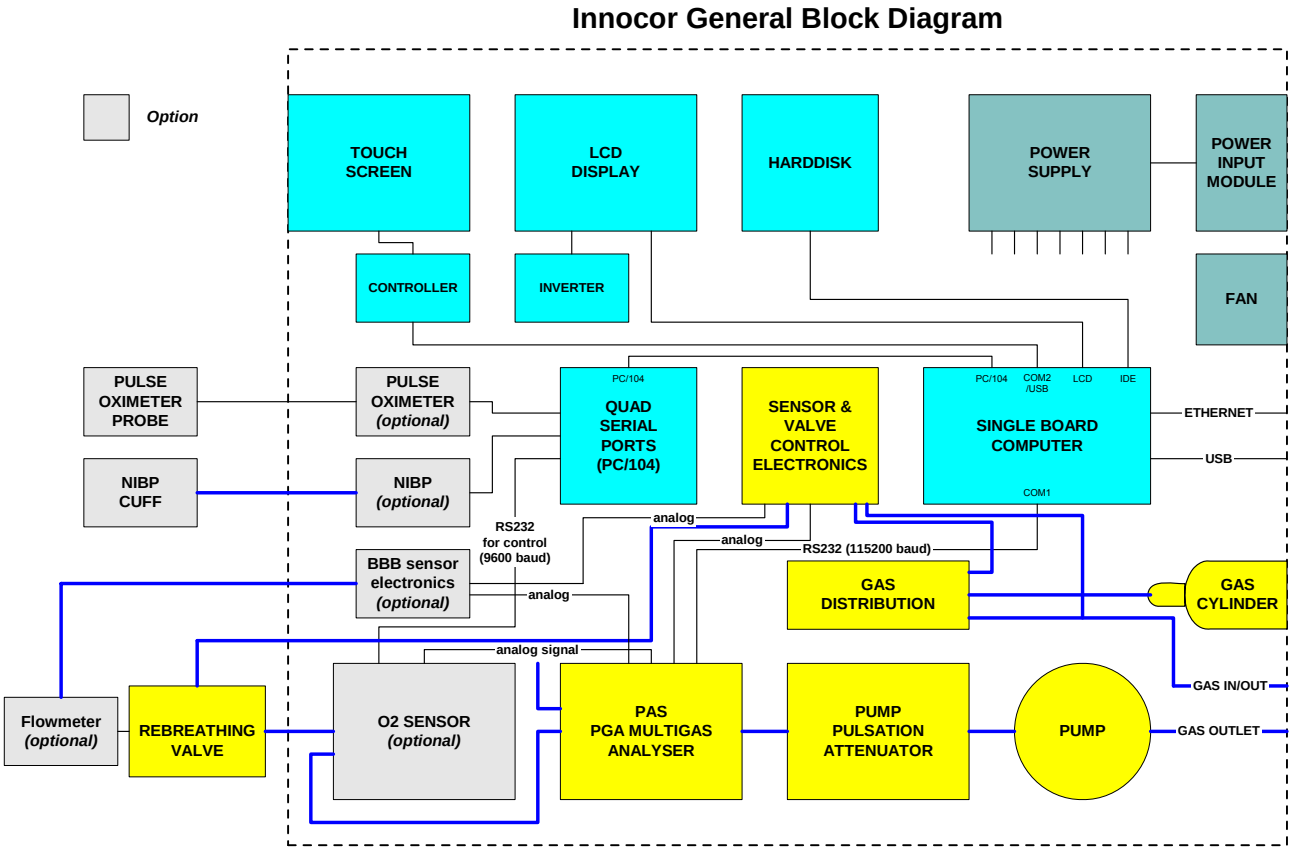


Figure 2.4-1 General block diagram.

The Innocor consist of the following main parts:
- High voltage (Power supply)
- An integrated computer
- Measuring system
- Optional sensors

The high voltage part converts the AC input voltage (110/230 V) to DC voltages used by the other subsystems (5 V, ±12 V).

The integrated computer consists of the following modules:
- Single board computer
- Hard disk
- LCD display (incl. inverter)
- Touch screen (incl. controller)
- Quad serial ports (with 4xRS232)

The computer controls the measurements of all sensors, and displays the results on the LCD display for the user. The user can operate the software using the touch screen only.

The measuring system consists of the following modules:
- PGA multigas analyser
- Inlet pump (incl. attenuator)
- Gas distribution system (incl. gas cylinder)

- Sensor & valve control electronics
- Rebreathing valves

The computer controls the PGA via a serial line. All digital and analogue lines are connected to the PGA via the I/F Board (sensor & valve control electronics). The gas distribution system reduces the pressure of the gas in the gas cylinder, and distributes the gas and air to different locations (bag filling of air or bolus, bag evacuation & pneumatic control of respiratory valve).

Optional sensors are:
- O2 sensor
- Pulse oximeter
- NIBP
- Flowmeter including BBB sensor electronics

The O2 sensor gives a measurement of the oxygen concentration and the oxygen consumption.
The pulse oximeter sensor gives a measurement of the heart rate and oxygen saturation.
The NIBP module is used to measure the blood pressure (diastolic, systolic and mean arterial pressure).
The BBB option includes a flowmeter and a BBB sensor electronics for the measurement of inspired / expired flow. The BBB sensor electronics is inserted between the sensor & valve control electronics (IF board) and the PGA.

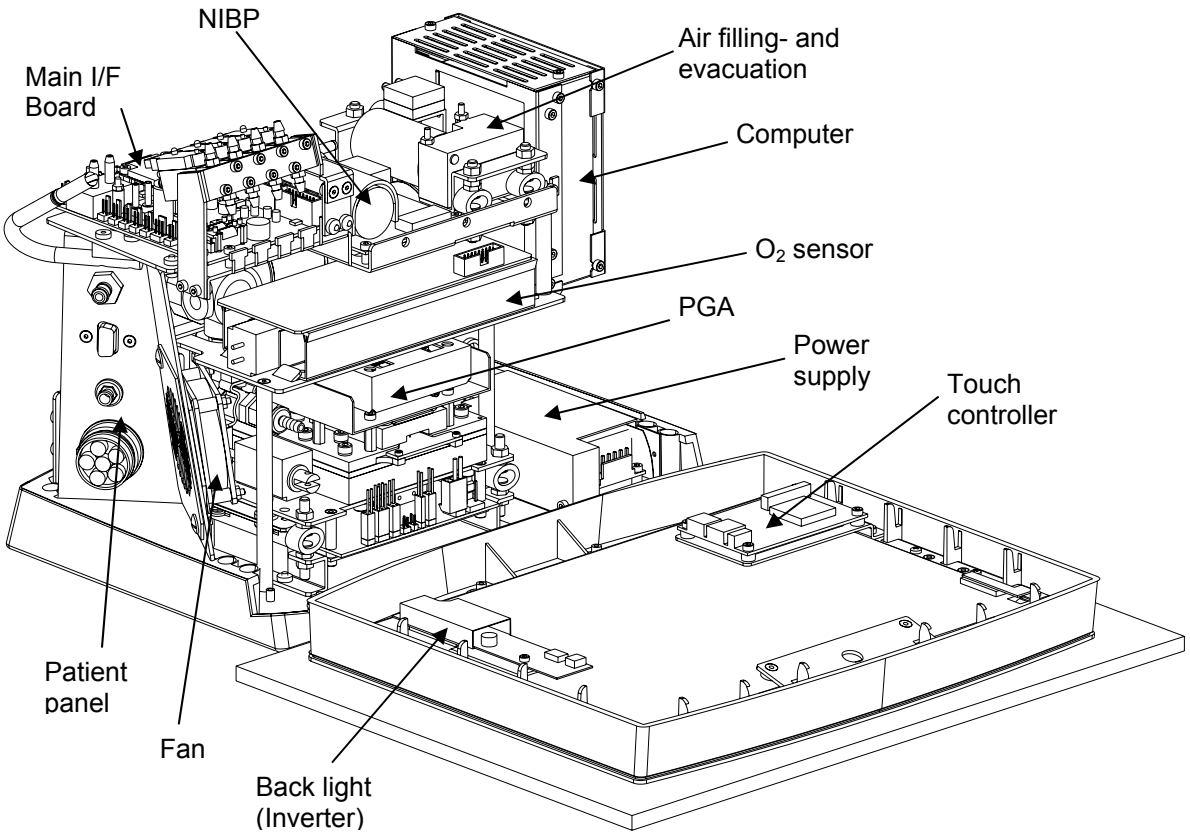


Figure 2.4-2 Innocor overview – seen from the front.

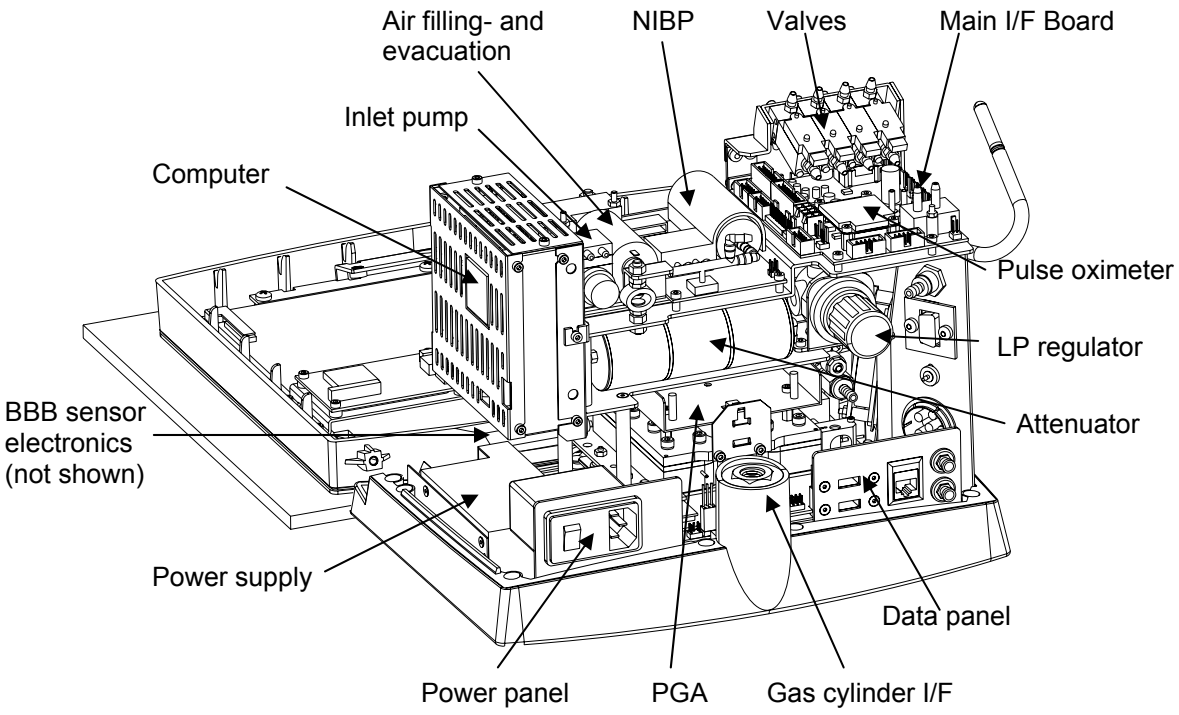


Figure *2.4*-3 *Innocor overview – seen from the back.*

2.5 PRINCIPLE OF OPERATION

2.5.1 Principle of CO_2, N_2O, SF_6 measurement

The PGA analyser measures the gas components: CO_2, N_2O and SF_6.

It is well known that among the gas species of interest in physiological examinations all except monoatomic gases, noble gases, nitrogen and oxygen absorb specific wavelengths of light in the infrared (IR) spectrum by intermolecular bindings. Therefore in acoustic gas measurements for medical applications Photo acoustic Spectroscopy (PAS) is used to determine all concentrations except for oxygen. When the gas is subjected to intermittent infrared (IR) light of different gas-dependent acoustic signals are produced and detected by a microphone.

Absorption of light means absorption of energy and causes a heating of the gases/vapours and thereby a rise in pressure.

By pulsation of the energy applied to the gas, the rise in pressure will be intermittent, thus causing a pressure fluctuation. By choosing the pulsation frequency in the audible range, the pressure fluctuation becomes an acoustic signal and it is possible to pick up the signal using a microphone.

2.5.2 Principle of O_2 measurement

The oxygen analyser is an Oxigraf O_2 sensor from Oxigraf Inc. US.

The patented Oxigraf sensor uses laser diode absorption spectroscopy in the visible spectrum, similar to the absorption method used to measure CO_2, N_2O, and SF_6 in the infrared spectrum. However, oxygen absorption is in a region of the visible spectrum (760 nm) where there is no interference or absorption by the other gases. Also the emission line width of the laser and the absorption line width of O_2 are very narrow, less than 0.01 nm, compared to perhaps 100 nm for

the CO_2 absorption band at atmospheric pressure. The spectrally pure laser is thermally tuned precisely to the oxygen absorption line. As the oxygen concentration increases, the light intensity is attenuated. The photo detector response varies linearly with the oxygen concentration.

2.5.3 Principle of flow measurement

The flowmeter contains a screen with a pressure output on each side of the screen. By measuring the pressure drop across the screen, the flow can be calculated.

2.5.4 Principle of pulse and S_pO_2 measurement

Oxygen saturation S_pO_2, expressed as a percentage, defines the amount of oxygen carried compared to total capacity. It is measured by a two-wavelength pulse oximeter.

The S_pO_2 value is measured by a light absorption technique: Red and infrared light (660 nm and 910 nm) is emitted from the emitter side of the sensor. The light is partly absorbed when it passes through the monitored tissue. The amount of transmitted light is detected in the detector side of the sensor. When the pulsative part of the light signal is examined, the amount of light absorbed by arterial hemoglobins is discovered and the saturation level can be calculated.

PATIENT HOOK-UP

- Connect the sensor to the S_pO_2 connector on the **Innocor** side panel.
- Attach the pulse oximetry sensor to the patient. It is recommended to use the index finger or middle finger.
- Remove finger nail polish, artificial nails etc. from the measuring site first.
- For proper sensor positioning, see the instructions for use accompanying each sensor.
- Do not pull the sensor from its cable.

PRECAUTIONS FOR USE

Pulse oximeters are not able to distinguish between HbCO, MetHb and HbO_2.

The saturation values may be somewhat higher for smokers. Special care should be taken with patients who have burns or carbon monoxide (CO) intoxication. When carbon monoxide intoxication is suspected, always confirm the pulse oximetry reading with a blood sample measurement.

Intravascular dyes may cause erroneous readings. For example, methylene blue, indigo carmine, indocyanine green or any substances that contain dyes, interfere with the S_pO_2 measurement.

2.5.5 Principle of blood pressure measurement

The non-invasive blood pressure (NIBP) measurement is an option, which may not be installed in your device.

It consists of an oscillometric NIBP module with a pressure transducer inside **Innocor**, a quick coupling on the side panel, a patient cable (air hose) and an arm cuff.

The pressure transducer converts the cuff pressure to an analogue output voltage, and also detects the small oscillometric waveforms resulting from the patient's arterial pulses. The oscillometric waveform is passed through a filter network (rejecting artefact and other noise) while being amplified.

After digitisation of the oscillometric signal the signal is further filtered (using software filtering techniques) before being used by the main algorithm to determine the systolic and diastolic points in the waveform. Simultaneously, the cuff pressure is measured directly from the transducer output. By combining the information provided by the oscillometric waveform and the cuff pressure, the systolic and diastolic blood pressures are determined. Analysis of the oscillometric waveform also provides information on the pulse rate.

PERFORMANCE

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff / stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or automated sphygmomanometers. The performance with common arrhythmias, such as atrial or ventricular premature beats or atrial fibrillation, has been verified by use of a patient simulator.

PATIENT HOOK-UP

The operating steps that are important for correct application are described below and include the selection of a suitable cuff size and correct positioning of the cuff.

It is important to select the cuff size that is appropriate to the diameter of the patient's upper arm. There are markings on the cuff indicating the limb circumference for which it is appropriate. Use the “RANGE FINDER” on the inside of the cuff to determine the correct size cuff to use.

There is a marking of the centre of the bladder, indicating the correct position for the cuff over the artery. Wrap the cuff around the arm making sure that the Artery Marker is aligned over the brachial artery as shown in figure 2.5.5-1.

Ensure that the air hose from **Innocor** to the cuff is not compressed, crimped or damaged.

Please, remember that using a cuff that is the wrong size may give false and misleading results.

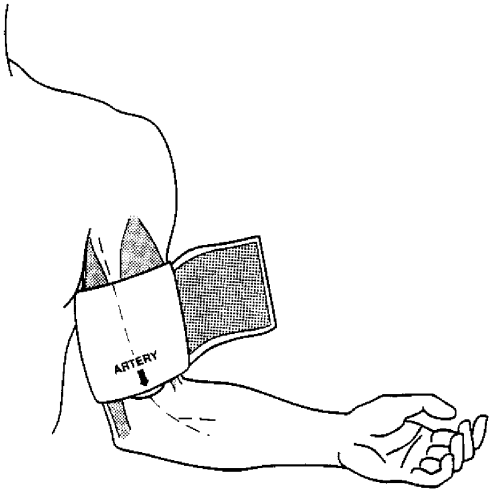


Figure 2.5.5-1 Cuff position on patient arm.

PRECAUTIONS FOR USE

To obtain accurate blood pressure readings, the cuff must be the correct size, and also be correctly fitted to the patient. Incorrect size or incorrect fitting may result in incorrect readings, refer to figure 2.5.5-1 above.

Blood pressure readings may also be affected by the position of the patient and his/her physiologic condition and other factors.

The NIBP option may not operate correctly, if used or stored outside the relevant temperature and humidity ranges.

The nominal range for the result of the blood pressure measurement is:

Systolic pressure: 40 to 260 mmHg
Diastolic pressure: 20 to 200 mmHg
Pulse rate: 40 to 200 BPM

2.5.6 Principle of gas filling

The rebreathing bag is filled prior to a test with an oxygen (O_2) enriched mixture containing two foreign gases; typically 0.5% nitrous oxide (N_2O) and 0.1% sulphur hexafluoride (SF_6). The filling is done in two steps:

- A bolus part is filled from the gas bottle containing 94% O_2, 5% N_2O and 1% SF_6.
- The rest is coming from air via an air pump.

Under normal resting conditions it is recommended to use 10% bolus and 90% air, which gives a mixture of:

- O_2 = 28.3%
- N_2O = 0.5%
- SF_6 = 0.1%

During exercise (>150 watt) it can be necessary to increase the bolus due to a higher oxygen uptake in order not to have too low oxygen (13%) concentration at the end of the test. The following formulae can be used to manual estimate the max Vo_2 during the test:

$$\text{Max } Vo_2 = ((0.2095-0.13)*V_{air} + (0.94-0.13)*V_{bolus}) / Time_{(sec)} * 60$$

Where

V_{air} = air volume
V_{bolus} = bolus volume
Time = rebreathing time

Knowing the Max Vo_2 the max work load can be predicted using the formulae:

$$\text{Max load (watt)} = (\text{Max } Vo_2 - 0.3) / 0.01$$

Examples of using different bag volumes, bolus concentration and rebreathing time:

V-bag (l)	1	1.5	1.5	2	2	2.5	2.5	3	3
Bolus (%)	10	10	15	10	15	10	15	10	15
Time (sec)	Max Vo_2 (l/min)								
10	0.9	1.4	1.7	1.8	2.3	2.3	2.8	2.7	3.4
12	0.8	1.1	1.4	1.5	1.9	1.9	2.4	2.3	2.8
14	0.7	1.0	1.2	1.3	1.6	1.6	2.0	2.0	2.4
16	0.6	0.9	1.1	1.1	1.4	1.4	1.8	1.7	2.1
	Max load (watt)								
10	62	107	140	153	197	199	254	245	310
12	46	84	112	123	159	161	206	199	254
14	35	68	92	101	132	133	173	166	213
16	27	56	76	84	112	113	147	142	183

The pluming diagram for the gas filling is shown in figure 2.5.6-1.

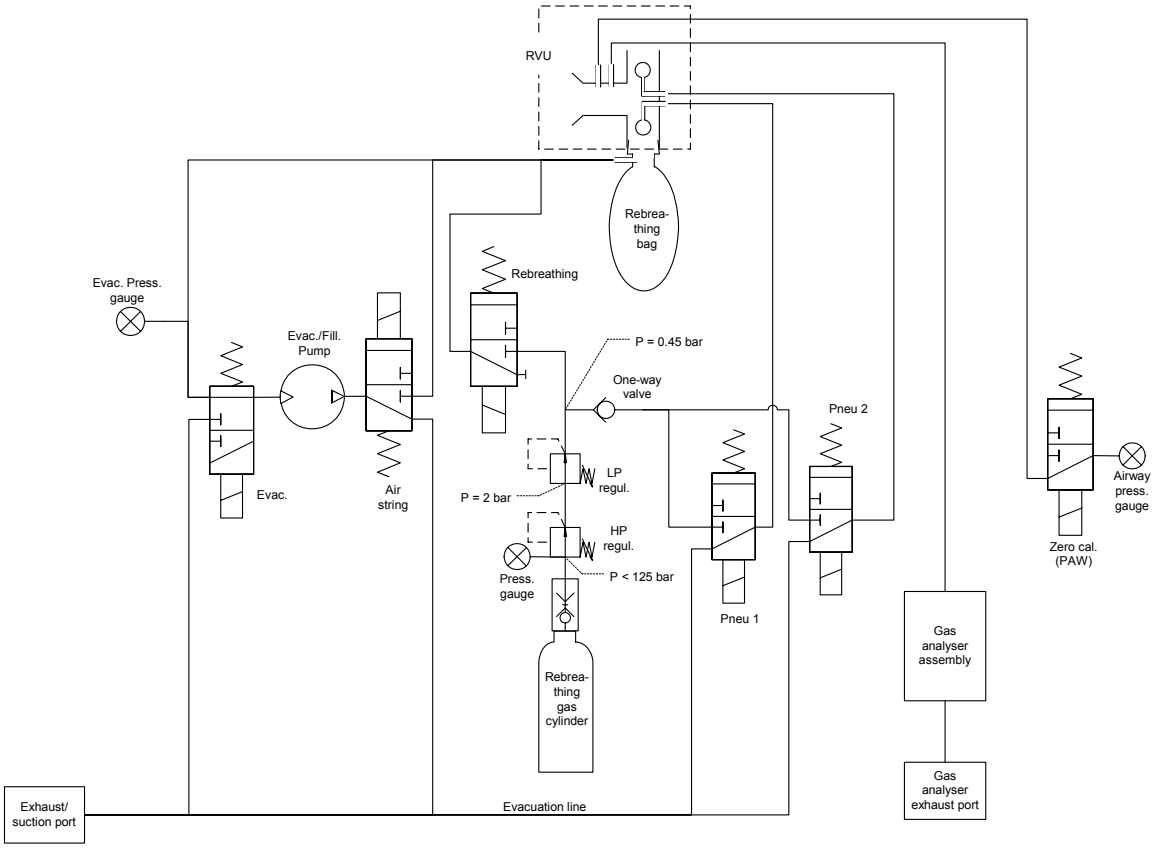


Figure 2.5.6-1 Gas filling diagram.

Bolus fill

The pressure in the gas bottle is up to 124 bar. The pressure is reduced to 2 bar (30 psi) in the first regulator, and further reduced to 0.45 bar in the second regulator. By controlling the opening time of the solenoid valve the bolus volume is controlled. Typical bolus filling flow is 20-70 ml/seconds.

Air fill

The pump does the air filling, and the volume is controlled by the on time. Typical air filling flow is 50-60 ml/seconds.

2.5.7 Principle of RVU control

The respiratory valve unit is pneumatically controlled. The pneumatic is coming from the gas bottle containing the bolus gas. The 0.45 bar is sufficient to activate the pneumatic elements in the RVU without damaging them. The port to the bag is closed by inflating the pneumatic element. When the rebreathing starts, the port to the rebreathing bag is opened by releasing the pressure of the pneumatic element, simultaneously with the closing of the port to ambient air.

The pluming diagram for the RVU control is shown in figure 2.5.7-1.

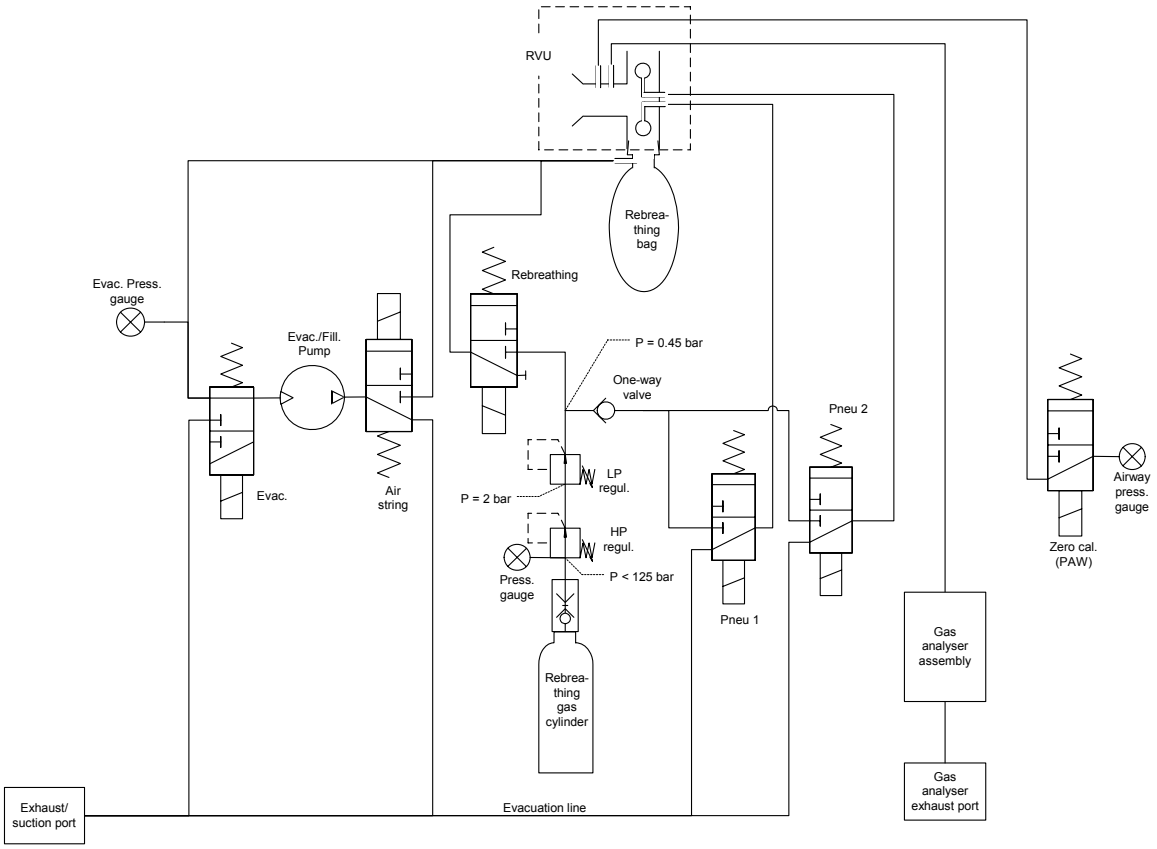


Figure 2.5.7-1 RVU control diagram.

2.6 WIRING DIAGRAM

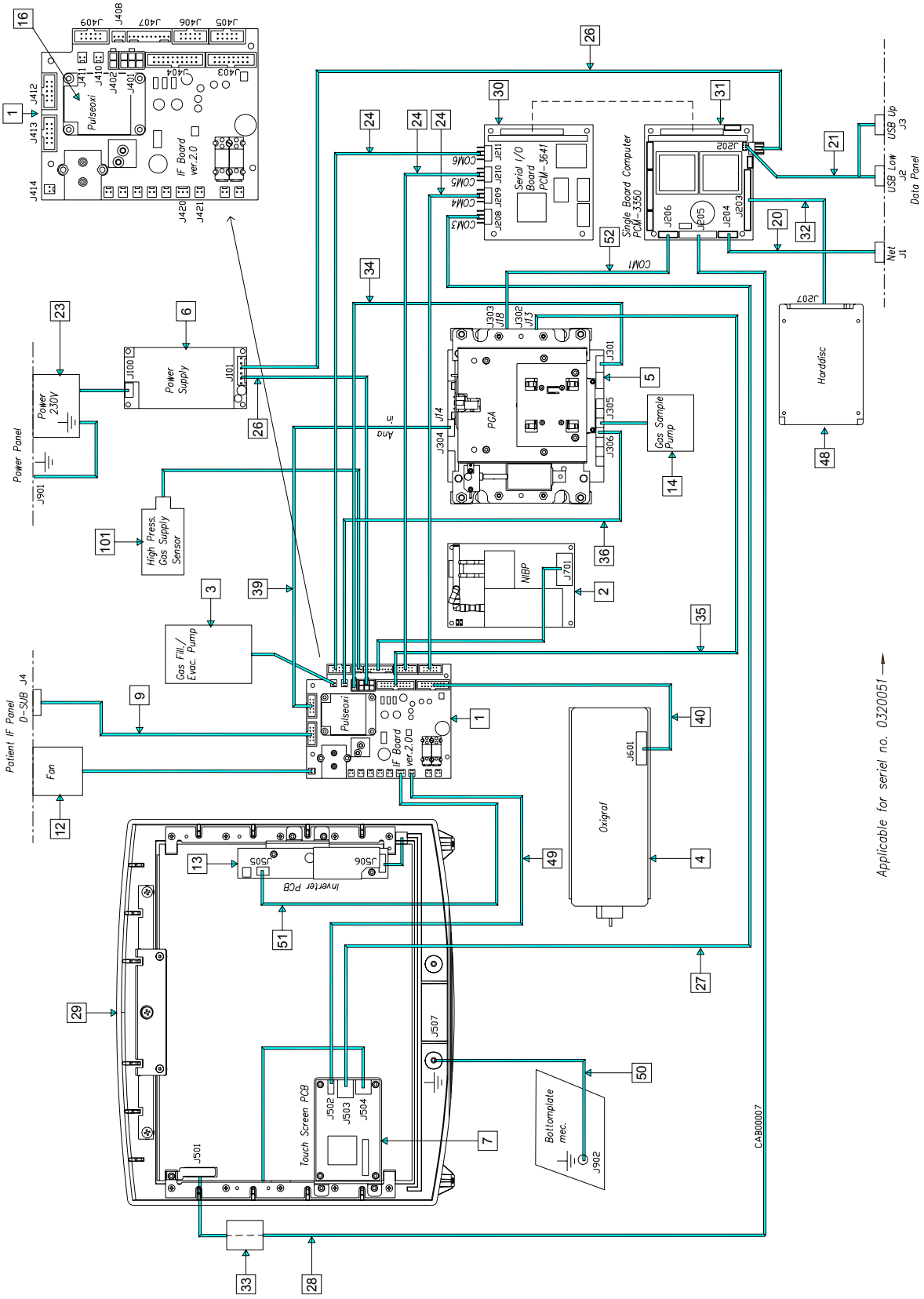


Figure 2.6-1 Wiring diagram without BBB (COR-DR-0000-0000-M90-IN-A/2).

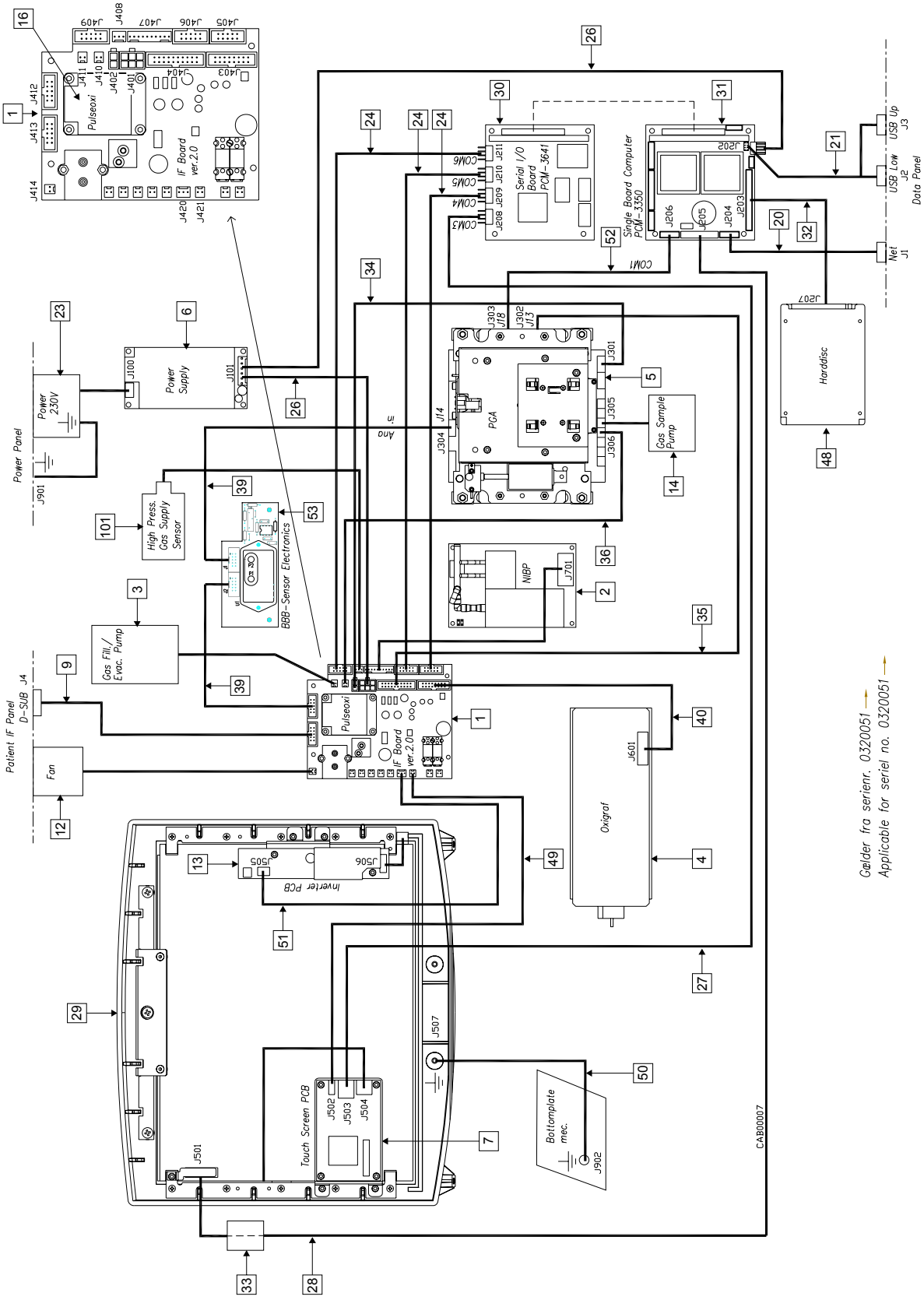


Figure 2.6-2 Wiring diagram with BBB (COR-DR-0000-0000-M90-IN-A/3).

2.7 TUBING DIAGRAM

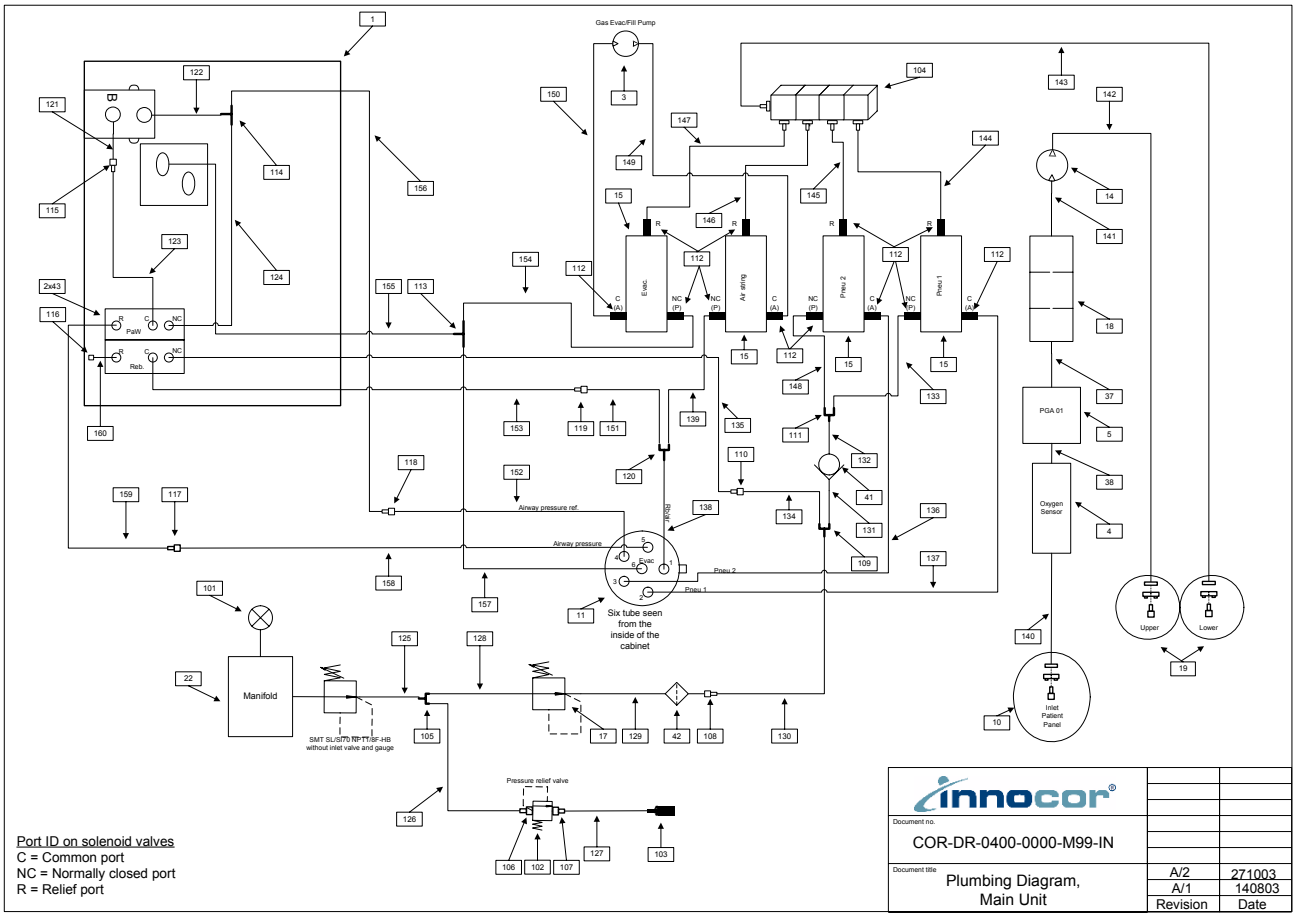


Figure 2.7-1 Tubing diagram without Breath-by-Breath.

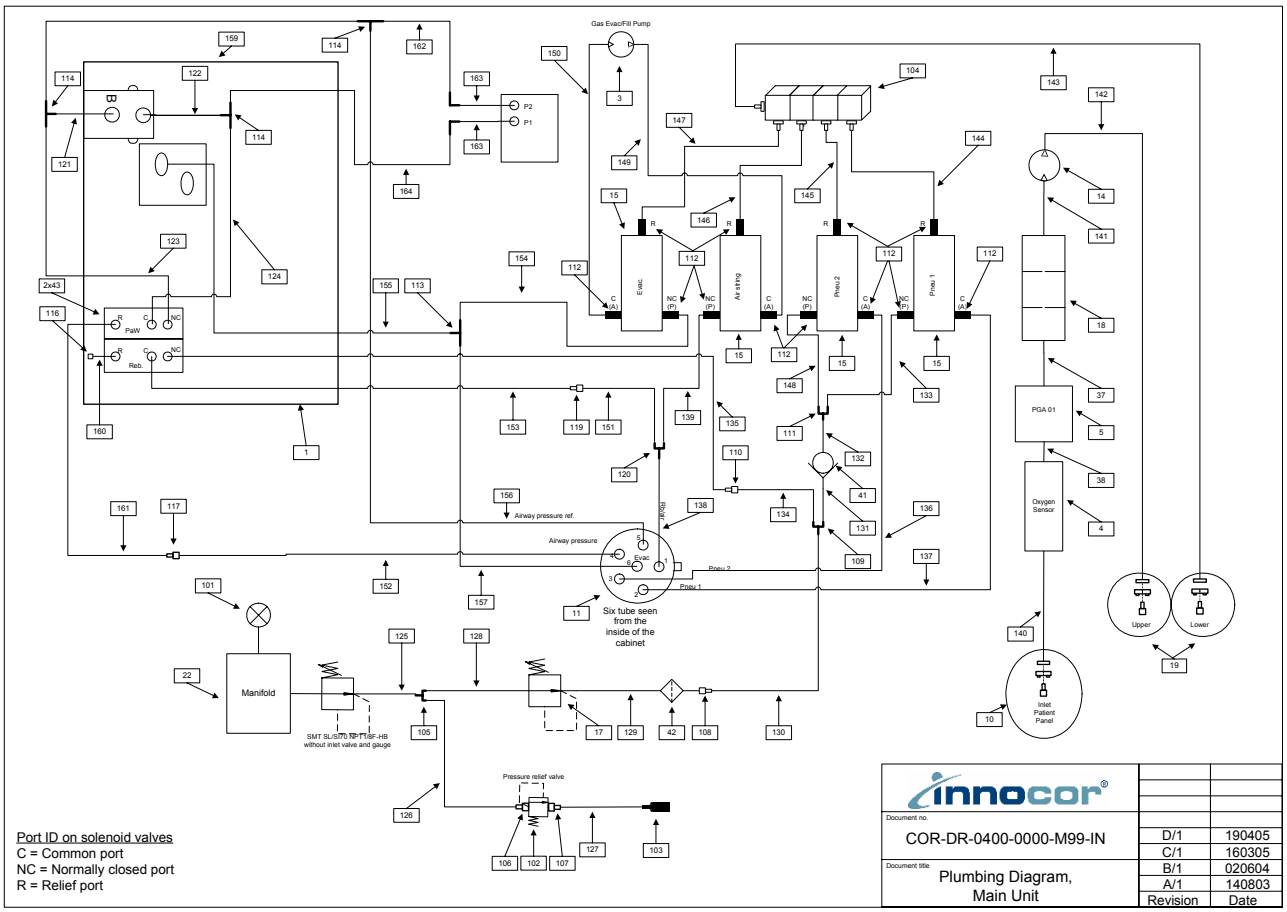


Figure 2.7-2 Tubing diagram with Breath-by-Breath.

2.8 EXTERNAL CONNECTOR CONFIGURATION

2.8.1 Pulse oximeter

A 9 Pin D-Sub connector

Pin	Cable colour	Description
7	Cable shield	Cable shield
5	Coax signal	Photo diode signal
8	Coax shield	Signal shield
9	Yellow	Photo diode bias
6	Green	Sensor type line
2	Red	LED drive line
3	Black	LED drive line

2.8.2 RVU

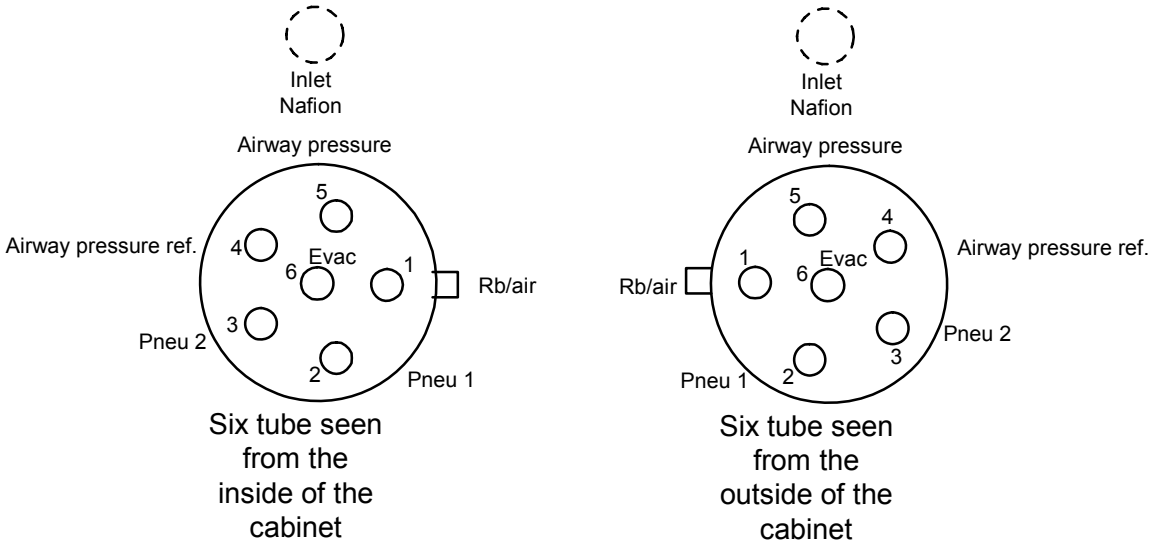


Figure 2.8.2-1 Six tube connector.

With BBB option:

Airway pressure ref. = flow port closest to the RVU
Airway pressure = flow port closest to the mouth piece

2.8.3 USB

Version: USB 1.1

A type A USB connector

Pin	Colour	Description
1	Red	+5 VDC
2	White	Data -
3	Green	Data +
4	Black	Ground

2.8.4 LAN

Speed: 10 / 100 Mbps
Type: Ethernet - TCP/IP

Pin	Colour	Description
1		Transmit Data + (TD+)
2		Transmit Data - (TD-)
3		Receive Data + (RD+)
4		Receive Data - (RD-)

3 DETAILED DESCRIPTION OF MODULES

3.1 GAS SAMPLING SYSTEM

The gas sampling is taken at the mouthpiece on the RVU. The gas is going through a Nafion Tube, which equilibrates the gas to the environment with respect to humidity. The gas passes a filter, which protects the analysers from dust and small particles. Next the gas passes the Oxigraf, where the oxygen level is analysed, and the PGA, where the other gas components are analysed. The PGA contains a flow-regulator, which controls the flow to approximately 120 ml/min. The gas passes an attenuator and finally the pump before the gas is leaving the outlet placed on the back of the Innocor. The purpose of the attenuator is to damp the pulsations from the pump.

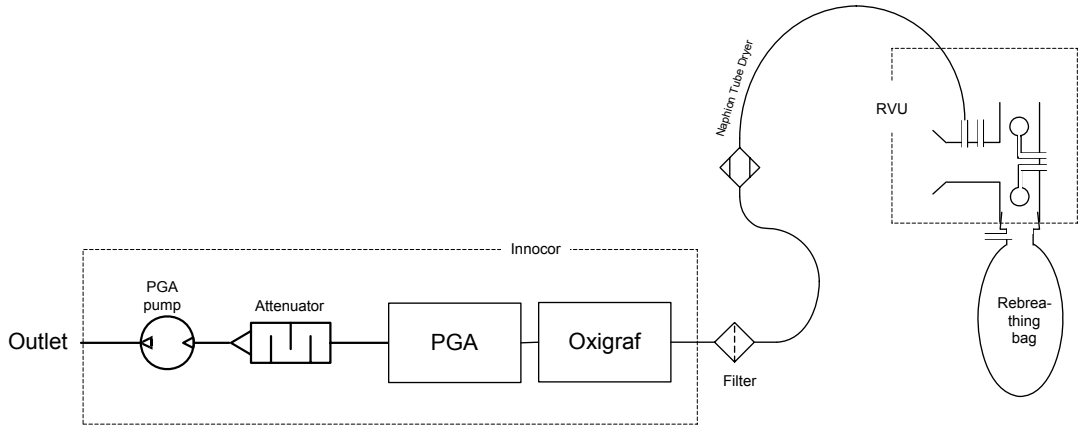


Figure 3.1-1 Gas sampling system.

3.2 CO_2, N_2O, SF_6 MEASUREMENT

The PGA analyser measures the gas components: CO_2, N_2O and SF_6. It consists of a measurement platform and a control electronics unit.

A photo of the PGA is shown in figure 3.2-1.

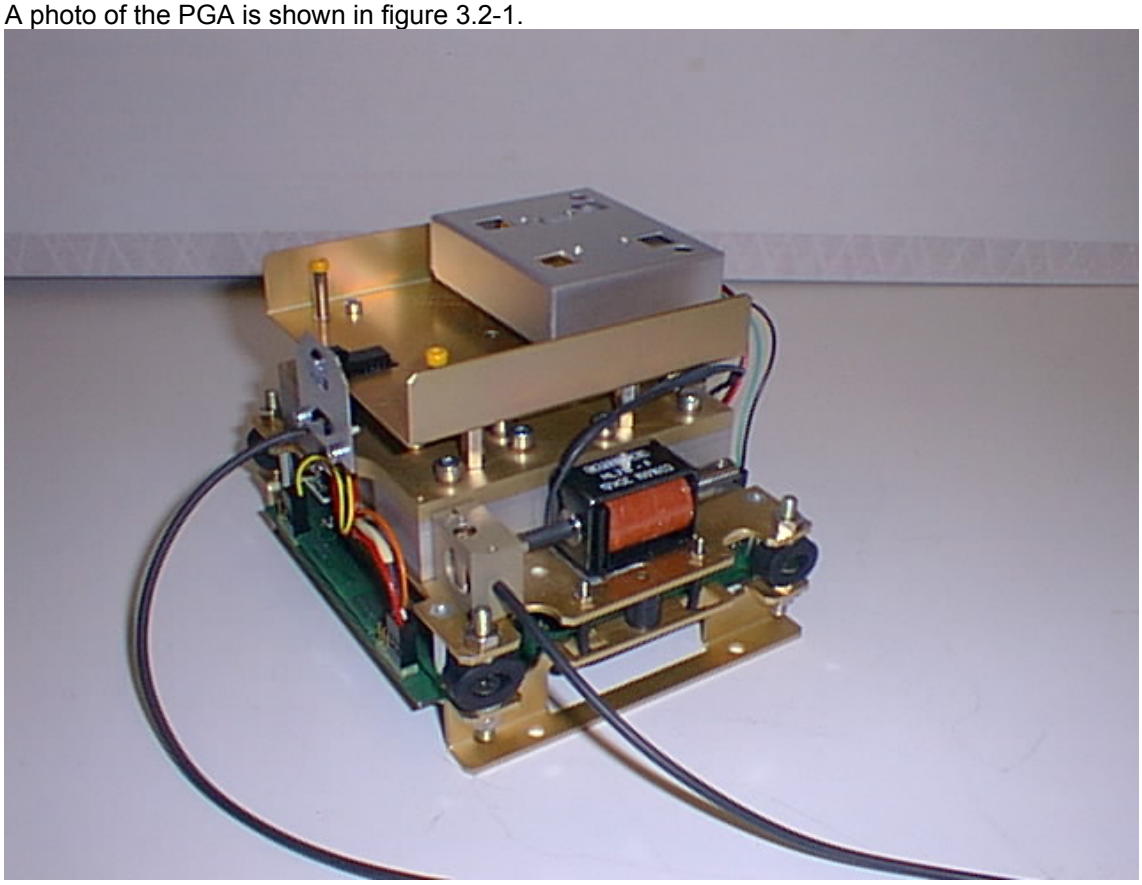


Figure 3.2-1 PGA analyser.

The PGA with gas sampling system consists of:

a) A platform structure equipped with shock absorbers to prevent vibrations to interfere with gas measurements.

b) A gas-sampling pump mounted independently of the measurement platform with vibration damping.

c) A Nafion sampling tube which ensures equilibration of the water vapour pressure of the sampled gas with that of the ambient air. The tube is connected to the RVU directly from the front panel.

e) Changeable bacterial filter.
The filter is implemented to protect the gas measuring system from particles in the air and from moisture and microorganisms from human breaths. The bacterial filter is fitted with a luer-lock fitting. The bacterial filter is changed periodically.

f) A flow regulator and associated flow control unit based on differential pressure measurement. The unit is used to keep the flow rate constant independent of the patient's airway pressure. The flow regulator can regulate the flow of the gas sampling pump from 0 ml/min to max. pump flow (500 ml/min).

g) A broadband infrared blackbody light source with ellipsoidal mirror.

h) A chopper wheel with DC motor.

i) An optical filter unit.

j) A measuring chamber, where the chopped infrared light excites the gas molecules.

k) Microphones.
The microphone measures the vibrations from the excited gas molecules.

l) An acoustic block.
The transport of sample gas and acoustic dampers is designed into one block.

The electronics consist of the following:

a) Digital Processor Board.

b) Analogue and power supply PCB.

c) Small PCB's which are condition units for PGA sensors.

It is well known that among the gas species of interest in physiological examinations all except monoatomic gases, noble gases, nitrogen and oxygen absorb specific wavelengths of light in the infrared (IR) spectrum by intermolecular bindings. Therefore in acoustic gas measurements for medical applications Photo acoustic Spectroscopy (PAS) is used to determine all concentrations except for oxygen. When the gas is subjected to intermittent infrared (IR) light of different gas-dependent, acoustic signals are produced and detected by a microphone.

Absorption of light means absorption of energy and causes a heating of the gases/vapours and thereby a rise in pressure.

By pulsation of the energy applied to the gas, the rise in pressure will be intermittent, thus causing a pressure fluctuation. By choosing the pulsation frequency in the audible range, the pressure fluctuation becomes an acoustic signal, and it is possible to pick up the signal using a microphone.

In terms of rise time and ambient noise suppression, a high pulsation frequency is desirable, but when choosing the pulsation frequency it has to be taken into consideration, that a high frequency results in a short time for the energy to have its effect on the gas, and this in turn means that a small signal is generated and that the sensitivity will be limited.

With an appropriate pulsation frequency, the amplitude of the signal is equivalent to the amount (concentration) of molecules in the measuring chamber.

Figure 3.2-2 and 3.2-3 shows a schematic representation of an acoustic measuring system as described above.

Light from an IR-source is reflected from a gold-plated elliptic mirror towards a window in a measuring chamber. Before it enters the measuring chamber it passes a spinning chopper-wheel, causing pulsation of the light. For analysis of different gases it is necessary to divide the IR-beam in different parts with respect to pulsation frequency as well as wavelength.

To accommodate this, the chopper wheel divides the IR-light in different beams with different pulsation frequencies, and each IR-light beam then passes individual optical filters. Each optical filter allows only a specific wavelength of light to pass through, and the different wavelengths of light correspond to the IR-absorption spectra of the gases/vapours, the system is designed to measure. See figure 3.2-4.

The IR-light beams differing in both pulsating frequency and wavelength enter the measuring chamber through a window and excite the different gases they are optimised for by the optical filters. Due to the absorption of energy the gas will expand in the chamber at frequencies equal to the pulsating frequencies of the IR-light beams. The periodic expansions of the gas/vapour are within the audible range (approx. 150-350 Hz) and a single highly sensitive microphone picks up the signals. Finally the different pressure signals are distinguished electronically (figure 3.2-5).

The following frequencies are used:

- SF_6 = 214.8 Hz
- CO_2 = 273.4 Hz
- N_2O = 332 Hz

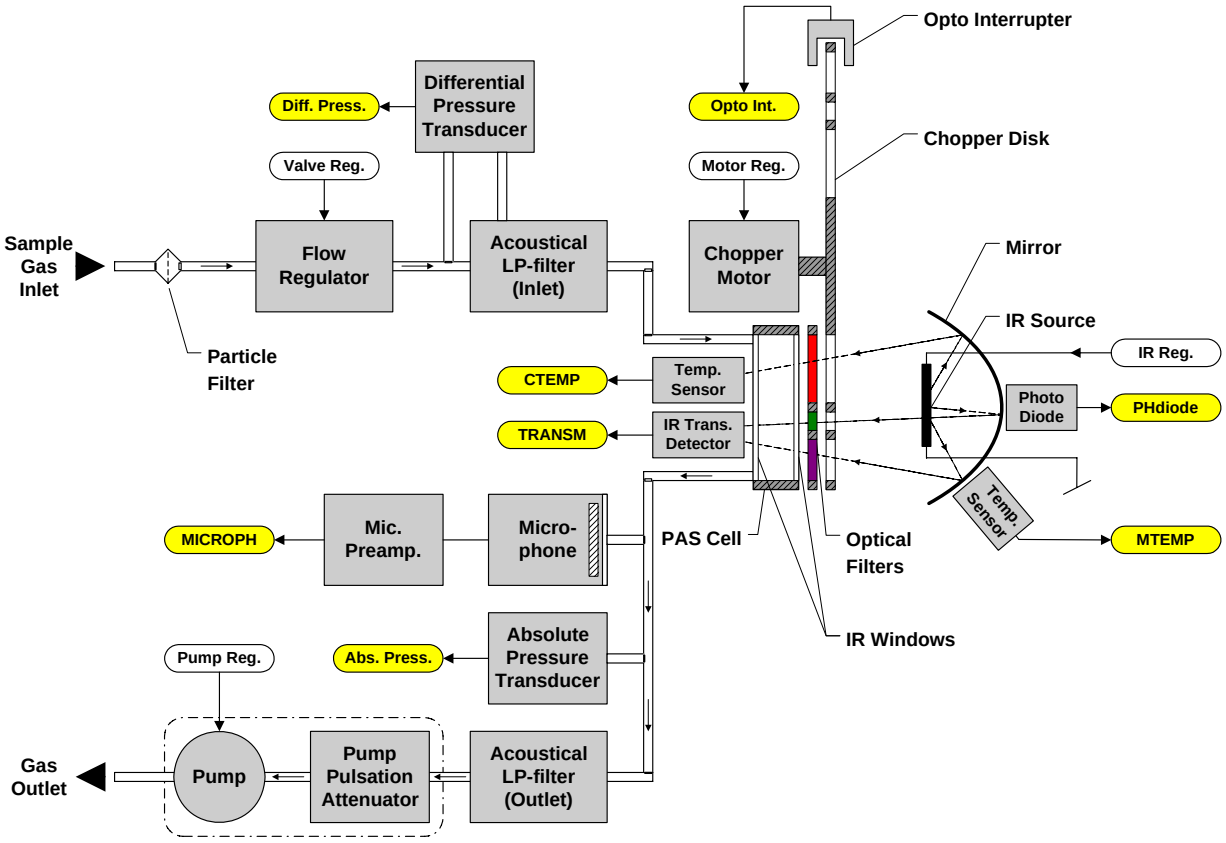


Figure 3.2-2 Schematic view of the acoustic measurement principles.

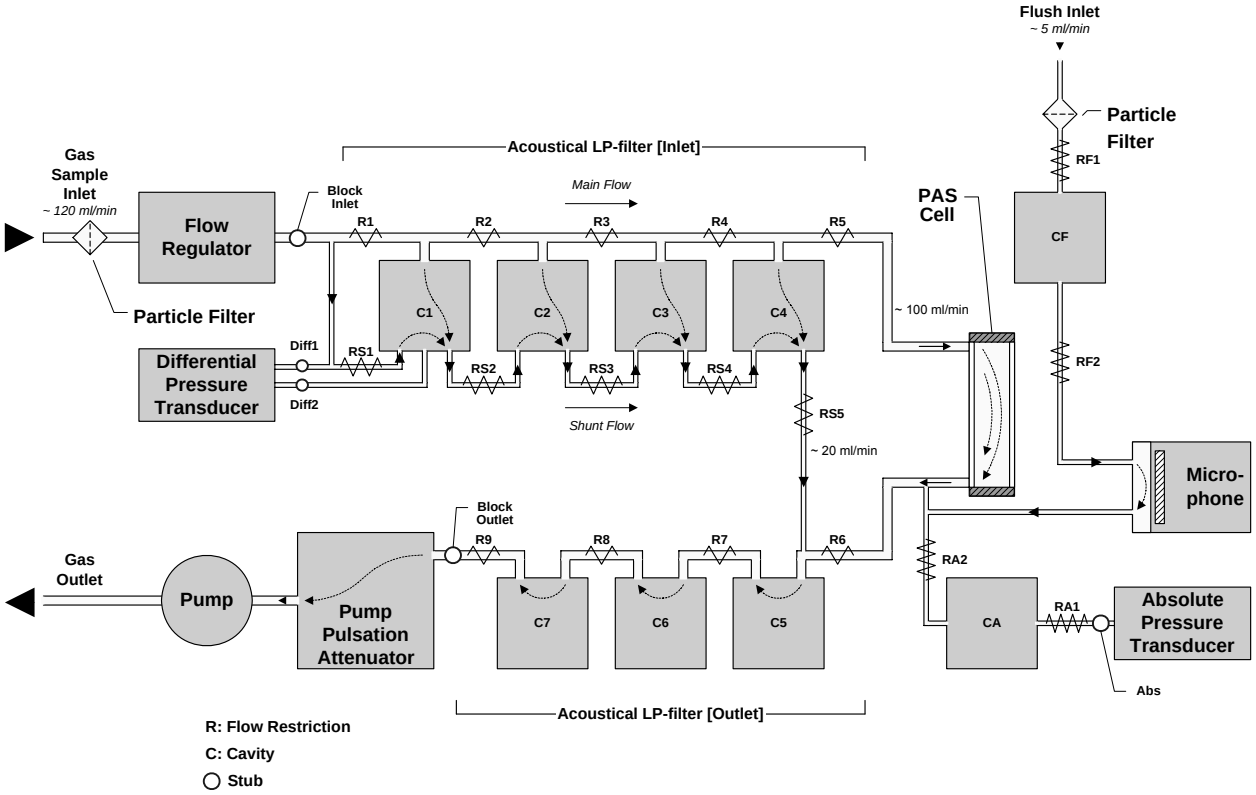


Figure 3.2-3 Schematic view of the gas flow.

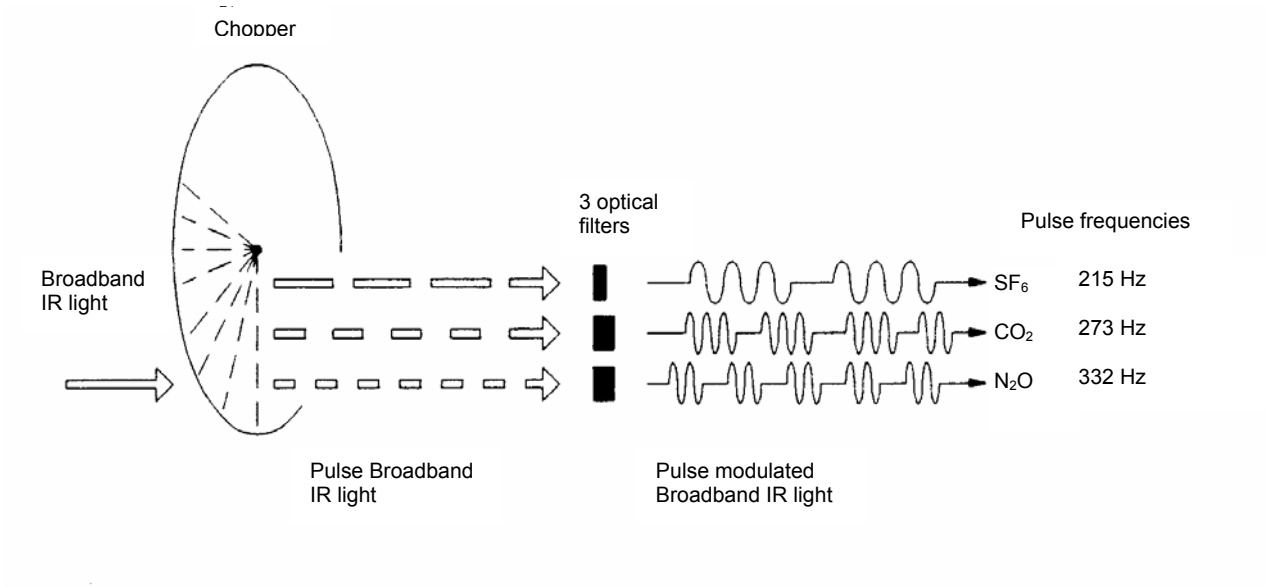


Figure 3.2-4 IR light chopping and filtering in the multi-gas analyser.

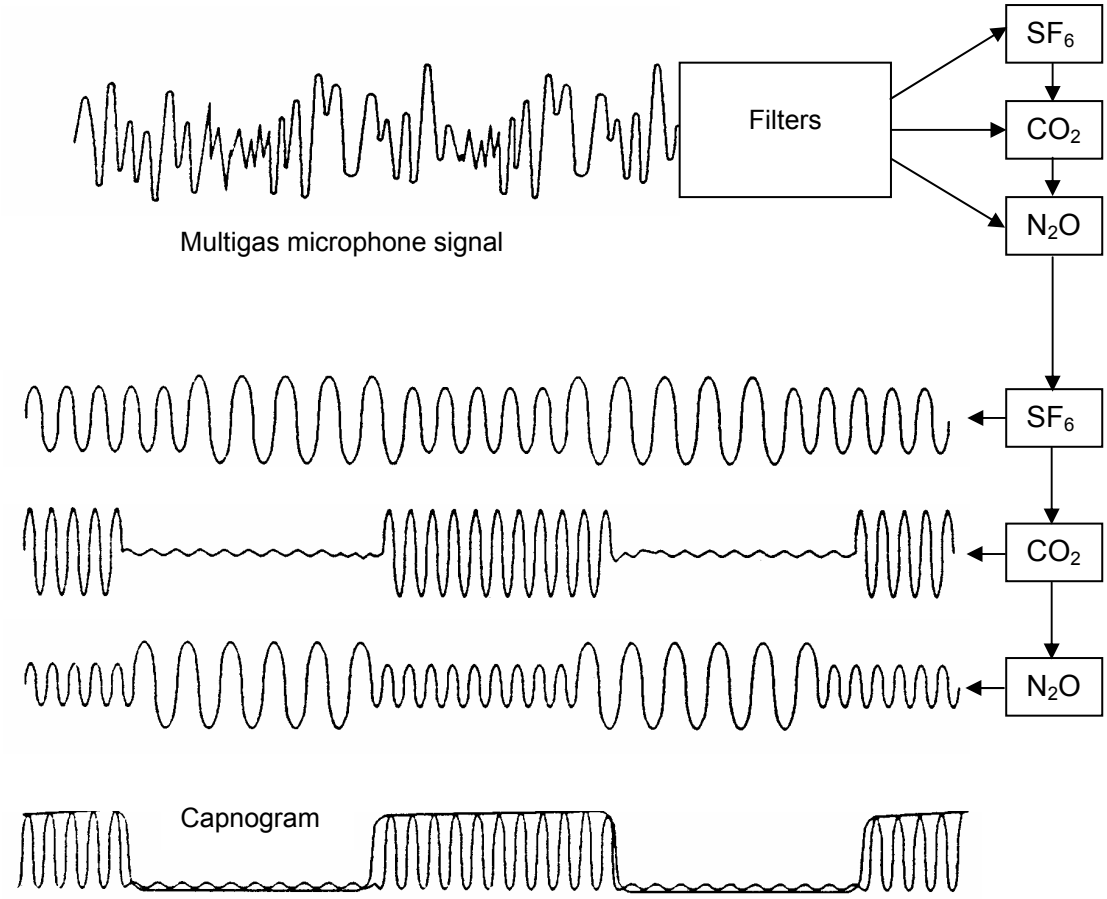


Figure 3.2-5 Principle of gas data processing.

3.3 O_2 MEASUREMENT

The oxygen analyser is the Oxigraf O_2 sensor model X1004/X2004 from Oxigraf Inc. US.
A picture of the Oxigraf is shown in figure 3.3-1 and a drawing in figure 3.3-2.

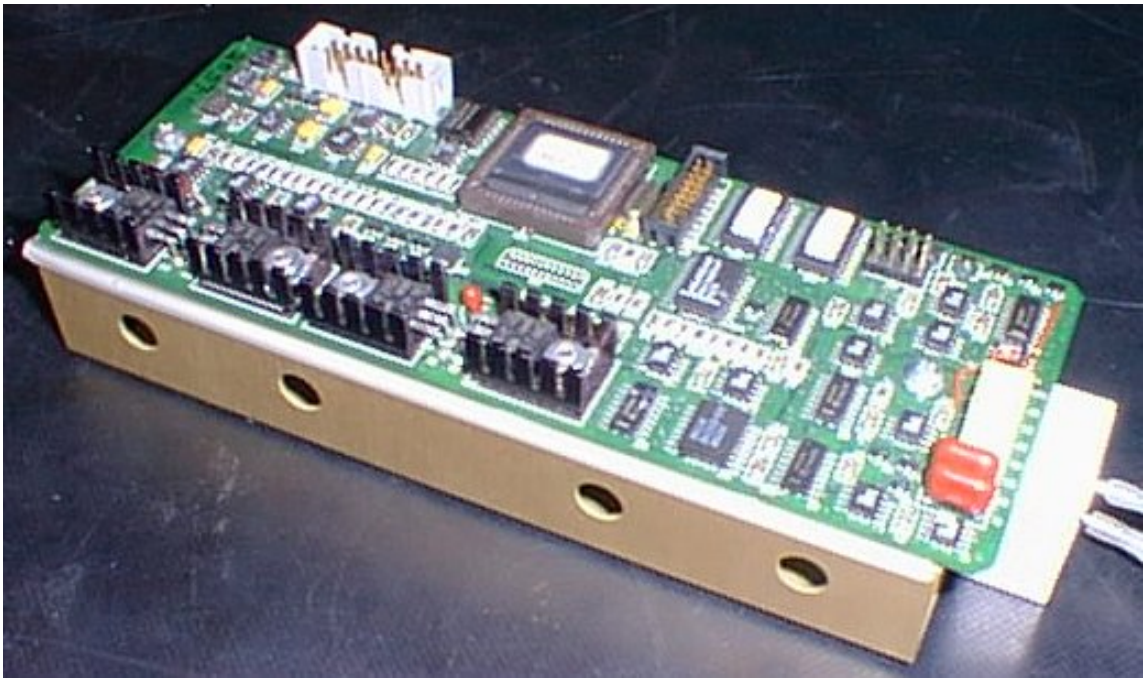


Figure 3.3-1 Oxigraf analyser

The Oxigraf is controlled via a serial line from the SBC. The oxygen measurement is acquired through an analogue output.

The oxigraf consists of 3 major parts:

- A measuring chamber with laser diode and detector
- A PCB with control electronics
- A mounting structure for PCB and measuring chamber.

In case of performance problems housekeeping data such as laser temperature, current and power can be acquired via the serial line.

The patented Oxigraf sensor uses laser diode absorption spectroscopy in the visible spectrum, similar to the absorption method used to measure CO_2, N_2O, and SF_6 in the infrared spectrum. However, oxygen absorption is in a region of the visible spectrum (760 nm) where there is no interference or absorption by the other gases. Also the emission line width of the laser and the absorption line width of O_2 are very narrow, less than 0.01 nm, compared to perhaps 100 nm for the CO_2 absorption band at atmospheric pressure. The spectrally pure laser is thermally tuned precisely to the oxygen absorption line. As the oxygen concentration increases, the light intensity is attenuated. The photo detector response varies linearly with the oxygen concentration. The measuring chamber with laser is shown in 3.3-3.

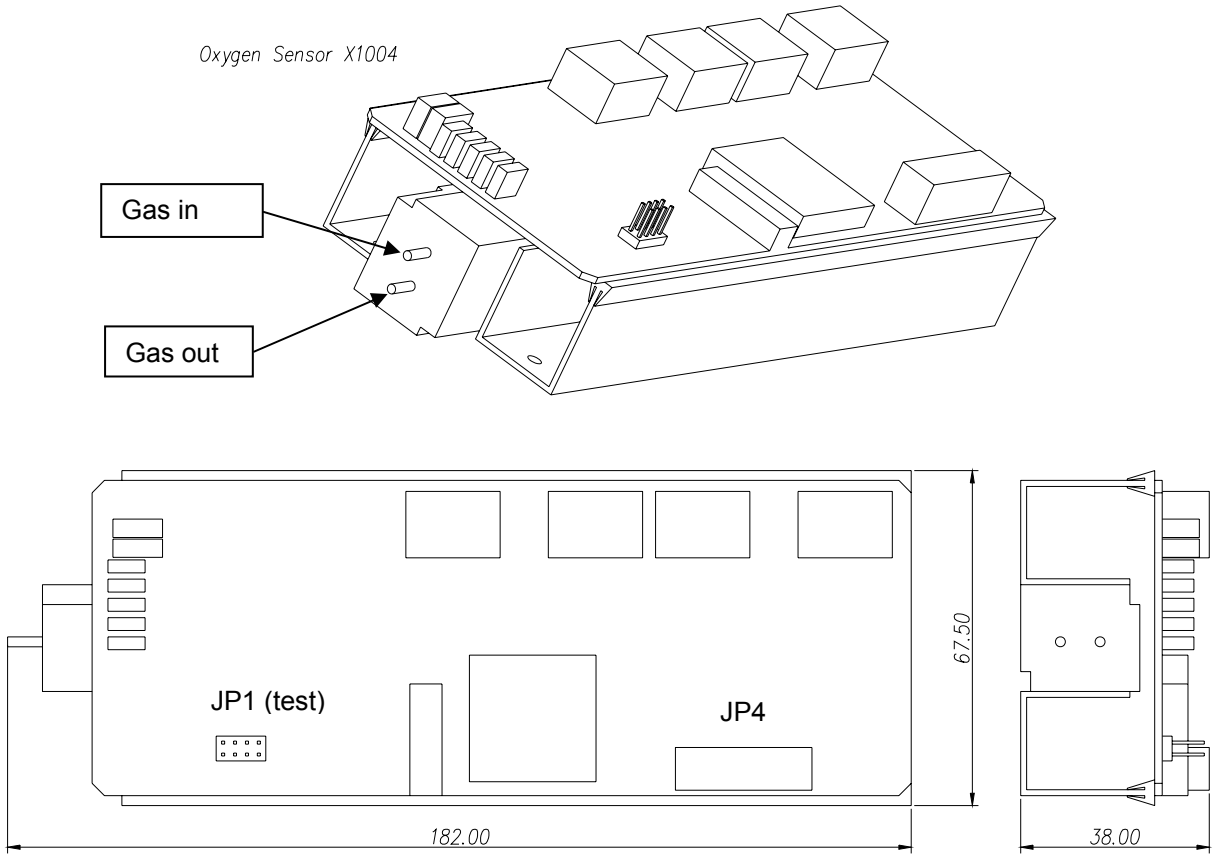


Figure 3.3-2 Oxigraf oxygen sensor.

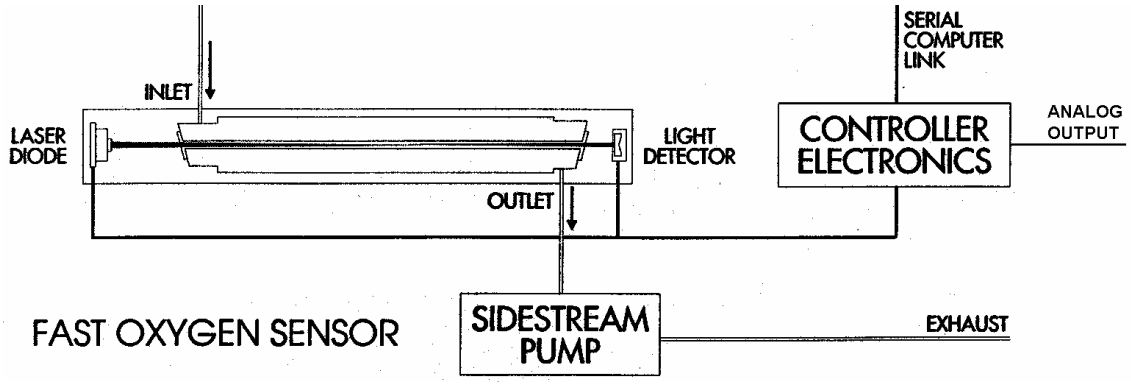


Figure 3.3-3 Oxigraf measuring chamber.

Background information

Different molecules absorb different amounts of electromagnetic radiation depending upon the frequencies of the radiation. A particular molecule therefore has a unique absorption spectrum of absorption versus radiation frequency. Figure 3.3-4 shows a number of absorption lines of gaseous oxygen located in the range of approximately 760 nm to 770 nm at Standard Temperature and Pressure. The relative height of the various peaks represents the relative absorption of the oxygen. Taller peaks represent more absorption. Shorter peaks represent less absorption. The baseline represents little or no absorption.

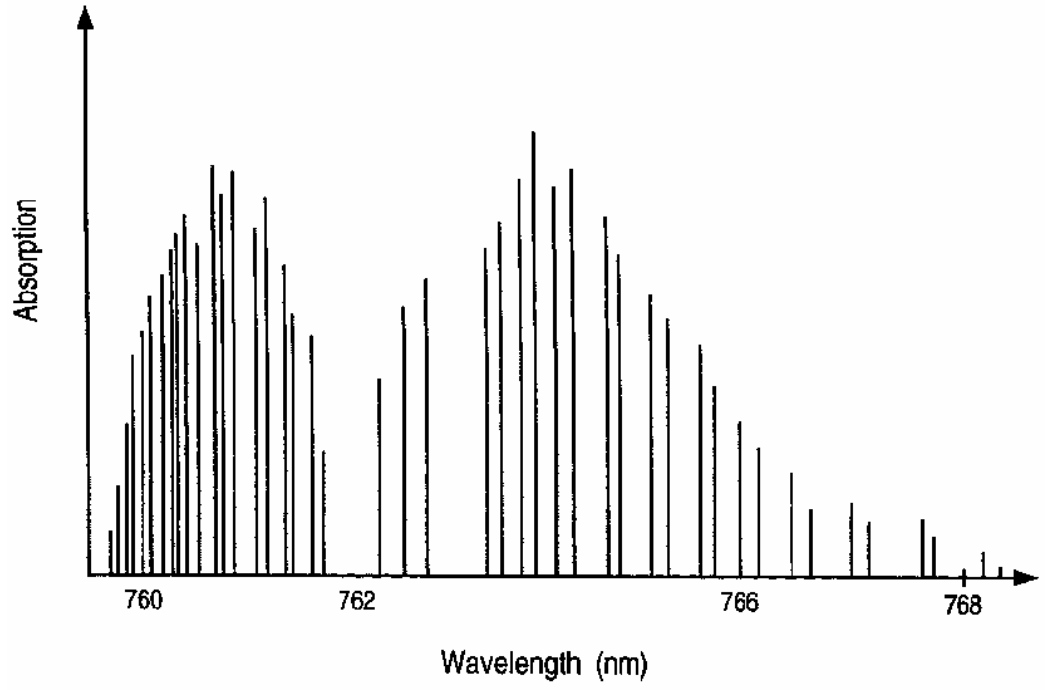


Figure 3.3-4 Oxygen absorption lines at STP.

The frequency (and therefore wavelength) of the radiation emitted from a laser diode-chip is dependent upon the physical dimensions of the laser diode chip as well as the current density through the laser diode chip. Because the size of a laser diode chip is temperature dependent, the wavelength of radiation emitted from a laser diode chip can be varied by varying the temperature of the laser diode chip.
Figure 3.3-5 is a diagram illustrating the wavelength of radiation generated by a laser diode versus temperature of the laser diode. The wavelength to temperature relationship, rather than being a linear relationship, has a stepped characteristic. As illustrated in figure 3.3-5, the wavelength of the emitted laser radiation increases gradually over some temperature ranges whereas the wavelength of the emitted laser radiation jumps in wavelength over other, relatively smaller, temperature ranges. The jumps in wavelength are called mode hops because the wavelength of the radiation emitted from the laser diode "hops" from one wavelength to another. A region of operation between two successive mode hops is called a "single mode”-operating operating region.
In order to generate laser radiation, an integral number of half waves of radiation must be reflected within the laser diode chip between two reflective surfaces of the laser diode chip. When the optical path length of a laser diode chip is changed within a single mode-operating region, the wavelength of the emitted laser radiation increases gradually with the change in laser diode optical dimension while the integral number of half waves reflected inside the laser diode does not change. When the dimensions of the laser diode chip are changed over a mode hop, however, the integral number of half waves suddenly changes thereby producing the hop in wavelength.
Because individual laser diodes typically are manufactured having slightly different physical dimensions at a given laser diode temperature, the wavelengths at which a number of laser diodes will experience mode hops typically varies from laser diode to laser diode. A spectral absorption line of a material which happens to occur at a wavelength corresponding with the wavelength of a

mode hop of a particular laser diode will result in the particular laser diode not being able to produce laser radiation of the proper wavelength corresponding to that spectral line. A small change in temperature will result in the particular laser diode generating laser radiation, which skips over the spectral line. Furthermore, a laser diode chip typically has a region of operation in which the laser radiation produced is not monochromatic. Two or more wavelengths of laser radiation may be simultaneously produced. This is known as "multi-modal" operation. Moreover, the temperatures at which such multi-mode laser diode operation occurs can change over the lifetime of a laser diode.
Despite the above-described problems associated with laser diodes, the Oxigraf nevertheless uses a laser diode to generate a highly monochromatic source of radiation, which is tunable to the wavelength of a spectral absorption line of a material under analysis. In, for example, the spectroscopic determination of concentration of oxygen, multiple relatively weak and narrow oxygen spectral absorption lines exist in the range of 760 nm to 770 nm at Standard Temperature and Pressure. Typical absorption of one of the stronger lines over a few inch path length in 100 percent O_2 is less than one percent. The width of such a spectral line is typically only about 4 pm. Although some of these oxygen absorption spectral lines may occur at the same wavelengths as the mode hops of a given laser diode, other of the oxygen absorption spectral lines generally will occur at different wavelengths where no mode hop exists. One particular oxygen absorption spectral line is therefore chosen for the individual laser diode chip of each individual oxygen concentration spectroscopy device. The particular oxygen absorption spectral line chosen is a preferably strong absorption peak which is well separated from any neighbouring absorption peaks and which is located in a single mode region of the particular laser diode away from the edges of a single-mode region of the laser diode. The emitted radiation from the particular laser diode can therefore be scanned in wavelength both above and below the wavelength of the particular spectral line chosen without leaving the single-mode operating region. This allows for future adjustment of the oxygen detector spectroscopy device over product lifetime. To determine the particular oxygen absorption spectral line for a particular laser diode, the wavelength of the laser radiation emitted from the particular laser diode is scanned during device manufacture from single-mode operating region to single-mode operating region until a suitable spectral line is found. Because operation of a laser diode at a low power can cause the laser diode to exhibit multi-modal behaviour and because operation of a laser diode at a very high power can cause the wavelengths of the mode hops to shift over laser diode lifetime, the laser diode is operated within maximum and minimum power range both during manufacture or during normal operation. For the type of laser diode having the characteristic represented in figure 3.3-5, operation at powers less than 1 mW commonly results in multi-modal radiation being emitted.

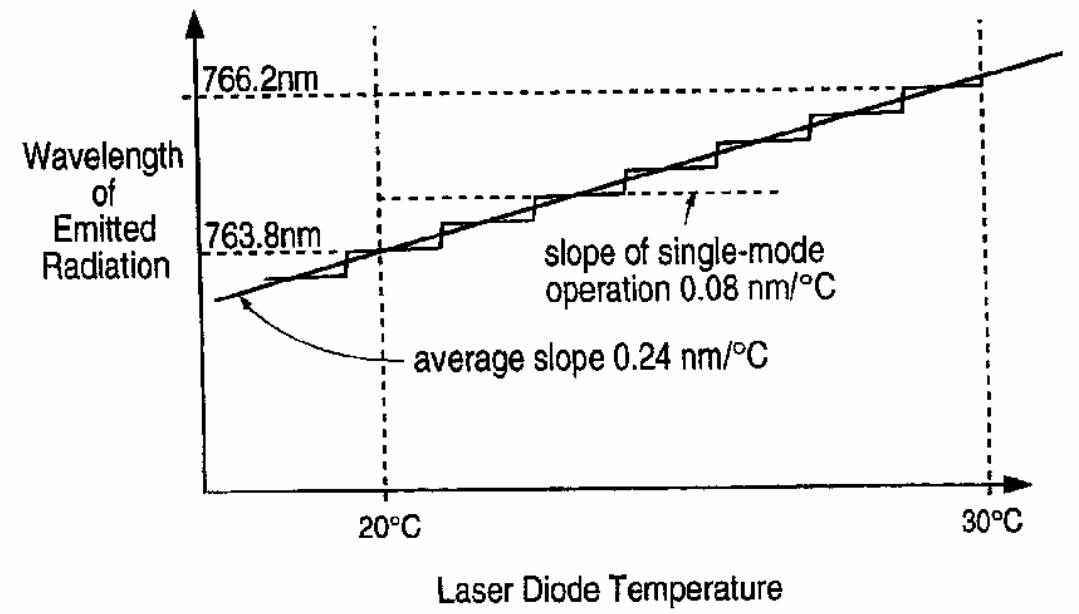


Figure 3.3-5 Wavelength of emitted radiation versus laser diode temperature.

Figure 3.3-6 is a simplified block diagram of the oxygen concentration spectroscopy device in the Oxigraf. A laser diode D1 emits a beam of laser radiation through a sample cell containing a sample of gas. The concentration of oxygen in the sample gas is to be measured. A monitor photo detector, (a photodiode), D2 is used to generate a signal indicative of the magnitude of the laser radiation supplied into the sample cell. A single photo detector (a photodiode), D3 is used to generate a signal indicative of the magnitude of the laser radiation, which is transmitted through the gas in the sample cell. Using the monitor photodiode D2 as a reference, the oxygen concentration spectroscopy device determines the relative amount of laser radiation, which is absorbed by the gas in the sample cell. A coarse adjustment of laser radiation wavelength is performed by coarsely controlling the temperature of the package or housing containing the laser diode. The temperature of the laser diode housing is cooled with thermoelectric coolers to the approximate laser diode temperature desired. The temperature of the laser diode housing is measured either by a thermistor in close thermal contact with the laser diode housing or by measuring the magnitude of the temperature-dependent forward voltage drop of the laser diode itself. Because the laser diode housing and the associated sample cell assembly has a relatively long thermal time constant, the control loop for cooling of the laser diode package via the thermoelectric coolers has a relatively slow response. Controlling the laser diode drive current supplied to the laser diode chip itself performs fine adjustment of laser radiation wavelength. Larger drive currents result in increased power dissipation of the laser diode chip. This results in increased laser diode gain and chip temperature. In contrast to the slow response time of the thermoelectric cooler control loop, the laser diode drive current control loop has a relatively fast response. Because the absorption lines of oxygen are so narrow, it is generally not possible to tune the laser radiation to the peak absorption wavelength of a desired spectral absorption line and to forever thereafter measure absorption through the sample cell. The wavelength of the radiation emitted from the laser diode is therefore frequently adjusted to keep the laser diode radiation "locked" onto the spectral absorption line of interest.

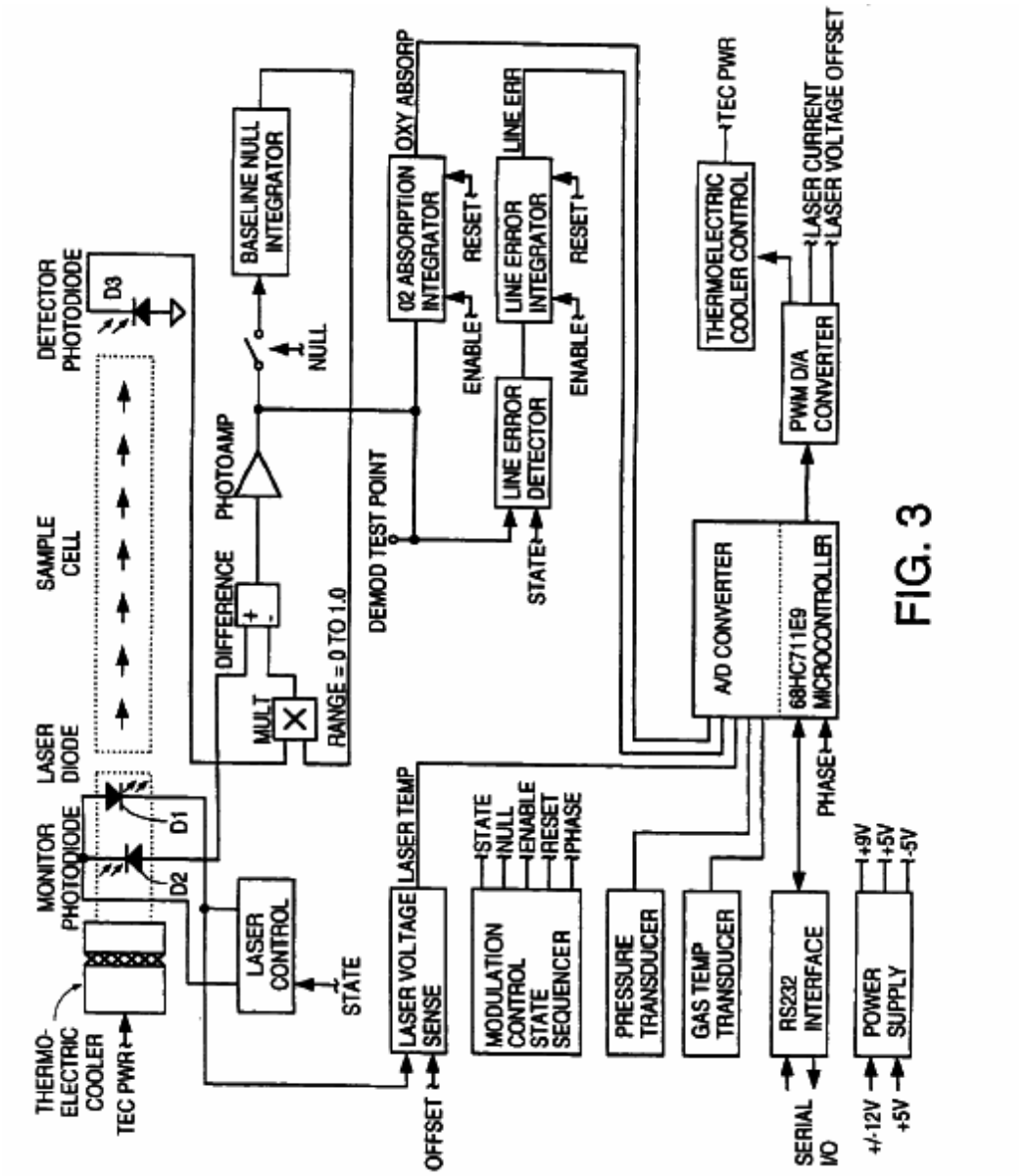


FIG. 3

Figure 3.3-6 Block diagram of Oxigraf.

Figure 3.3-7 is a diagram illustrating a spectral absorption line 40 in relation to the operation of the oxygen concentration spectroscopy device of figure 3.3-6 when the oxygen concentration spectroscopy device is "locked" onto the spectral absorption line 40. The spectral absorption line illustrated in figure 3.3-7 is drawn having an exaggerated width WI for illustration purposes. The laser diode D1 of figure 3.3-6 is controlled to emit laser radiation of five different wavelengths: a left baseline wavelength w_{bl}, a left skirt wavelength w_{sl}, a peak wavelength w_p, a right skirt wavelength w_{sr}, and a right baseline wavelength w_{br}. The left baseline wavelength w_{bl} is located several line widths lower in frequency than is the left skirt wavelength w_{sl}. Similarly, the right baseline wavelength w_{br} is located several linewidths higher in frequency than is the right skirt wavelength w_{sr}. The baseline wavelengths w_{bl} and w_{br} are generated to determine the relative amount of radiation which passes through the sample cell with little or no absorption in the sample cell versus the amount of radiation introduced into the sample cell. The skirt wavelengths w_{sl} and w_{sr} are generated to determine the degree to which the peak wavelength w_p of the radiation emitted from the laser diode differs from the actual wavelength of the peak of the absorption line. The difference between the peak wavelengths w_p generated by the oxygen concentration detector and the wavelength of the peak of the actual spectral line is called the line lock error. In figure 3.3-7 the magnitudes of the absorption at the left skirt wavelength w_{sl} and the right skirt wavelength w_{sr} do not differ from one another so the oxygen concentration detector is said to be "locked" onto the

absorption line 40. The peak wavelength w_p is generated so that the magnitude of the radiation detected to have passed through the sample cell at the peak wavelength w_p can be subtracted from the magnitude of the radiation detected to have passed through the sample cell at the baseline wavelengths and w_{bl} w_{br} to generate a measure of radiation absorbed in the sample cell. Figure 3.3-8 is a diagram illustrating a spectral absorption line 40 in relation to the operation of the oxygen concentration detector of figure 3.3-6 when the oxygen concentration detector is not perfectly "locked" onto the spectral absorption line 40. If the magnitudes of the radiation detected at the left and right skirt wavelengths differ from one another as illustrated in figure 3.3-8, then the peak wavelength of the actual spectral line is determined not to be centred between the two skirt wavelengths. The baseline, skirt and peak wavelengths in figure 3.3-8 should be shifted downward in frequency to achieve optimal line lock.

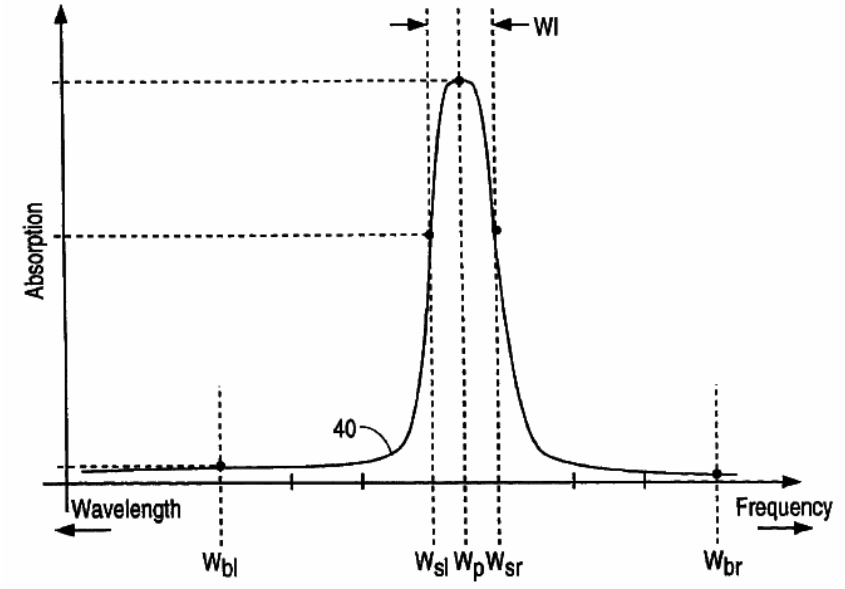


Figure 3.3-7 "Locked" spectral absorption line.

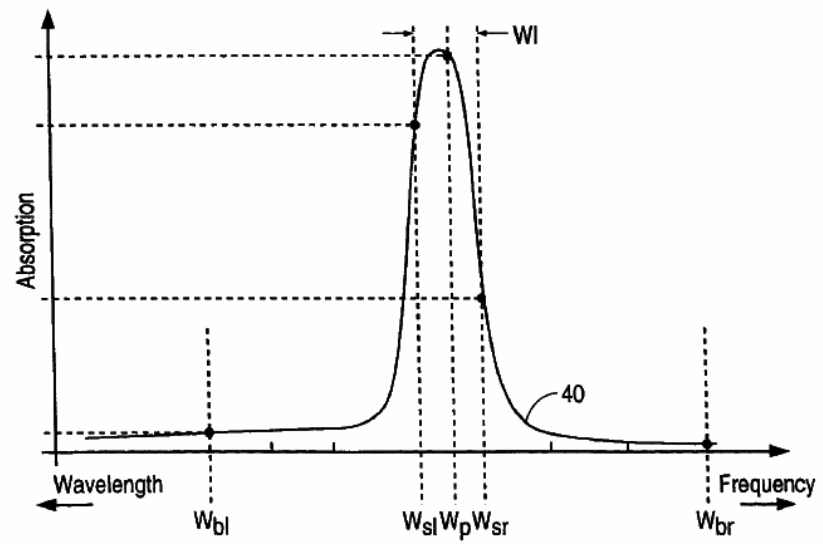


Figure 3.3-8 "Unlocked" spectral absorption line caused by an imbalance in w_{sl} and w_{sr}.

The simplified block diagram of figure 3.3-6 illustrates how the radiation detected at the baseline

wavelengths can be subtracted from the radiation detected at the peak and skirt wavelengths so that the results are indicative of the skirt and peak absorbencies of the material in the sample cell. A difference circuit labelled DIFFERENCE detects the difference in current between its two inputs leads. The current from the monitor photo detector D2 is supplied to one of the input leads of this difference circuit. The current from the detector photodiode D3 is, however, not supplied directly to the difference circuit. Rather, the current from the detector photodiode D3 is supplied to an input lead of a multiplier circuit labelled MULT and the output of the multiplier circuit MULT supplies the current to the second input lead of the difference circuit. In operation, there are five basic time intervals. During a first time interval, the left baseline wavelength w_{bl} is generated; during a second time interval the left skirt wavelength w_{sl} is generated; during a third time interval the peak wavelength w_p is generated; during a fourth time interval the right skirt wavelength w_{sr} is generated; and during a fifth time interval the right baseline wavelength w_{br} is generated. During the baseline wavelength time intervals, a null switch is closed by the signal labelled NULL. A baseline null integrator controls the second input lead of the multiplier circuit so that the magnitude of the current supplied to the second input lead of the difference circuit from the signal photo detector D3 exactly equals the magnitude of the current supplied to the first input lead of the difference circuit from the monitor photo detector D2. After the baseline interval, the null switch is opened so that the baseline null integrator will maintain this condition during the skirt and peak time intervals when the absorption at the skirt and peak wavelengths is detected. As a result, the difference between the monitor photo detector current during the baseline intervals and the signal photo detector current during the measurement of sample cell absorption at the skirt and peak wavelengths is detected. If oxygen is present in the sample cell during skirt and peak intervals, the voltage of the signal output from the photo amplifier labelled PHOTOAMP will be negative during the skirt and peak intervals. The circuit labelled O2 ABSORPTION INTEGRATOR to derive an unscaled output signal OXY ABSORP integrates this voltage signal. OXY ABSORP is indicative of the amount of oxygen absorption due to the spectral line. Integration is used, rather than simple sampling of the peak photo amplifier output, in order to provide noise reduction. The magnitude of the signal OXY ABSORP is read by an on-chip A/D converter of a micro controller. The micro controller determines percent oxygen based on the value of the OXY ABSORP signal. A measure of the line lock error is required to maintain the radiation of the laser diode locked onto the absorption line of interest. The line error detector labelled LINE ERROR DETECTOR in figure 3.3-6 inverts the magnitude of the voltage signal output from the photo amplifier PHOTOAMP during the right skirt interval. Both the non-inverted left skirt photo amplifier voltage output and inverted right skirt photo amplifier voltage output are integrated by a line error integrator circuit labelled LINE ERROR INTEGRATOR in figure 3.3-6. The output of the line error integrator after both the left and right skirt intervals is integrated is a measure of the line lock error. The micro controller reads the integrated line lock error signal LINE ERR via the A/D converter and adjusts the laser diode drive current and/or thermoelectric cooler current to adjust the wavelengths w_{bl}, w_{sl}, w_p, w_{sr} and w_{br} in order to correct those wavelengths with respect to the actual wavelength of the peak of the absorption line. When the oxygen concentration spectroscopy device is first turned on, the wavelengths of the laser radiation emitted from the laser diode are forced to the particular absorption line preselected for operation during device manufacture. The forward voltage drop across the laser diode is therefore detected by a laser voltage sense circuit labelled LASER VOLTAGE SENSE in figure 3.3-6 and the signal output from the laser voltage sense circuit is read by the micro controller as an indication of laser diode temperature. The micro controller uses the signal output from the laser voltage sense circuit as a measure of laser diode temperature so that the micro controller can control laser diode temperature through the thermoelectric coolers and laser diode drive current such that laser radiation of wavelengths corresponding to the preselected spectral line are generated. In some embodiments, a thermistor disposed in thermal contact with the housing of the laser diode is used by the micro controller to detect laser diode temperature.

3.4 FLOWMETER

The flowmeter consists of 4 parts. A fine screen/mesh is held in position by 2 parts, which again are held in position by a locking ring. See figure 3.4–1 for details. The screen must be replaced when dirty or if water/saliva has passed the filter and entered the screen.

Flowmeter volume:	60 ml (total)
Filter port:	30.2 mm Ø (conic)
RVU port:	34.50 mm Ø
Flow resistance:	8-10 cm H_2O @ 5 l/s including RVU

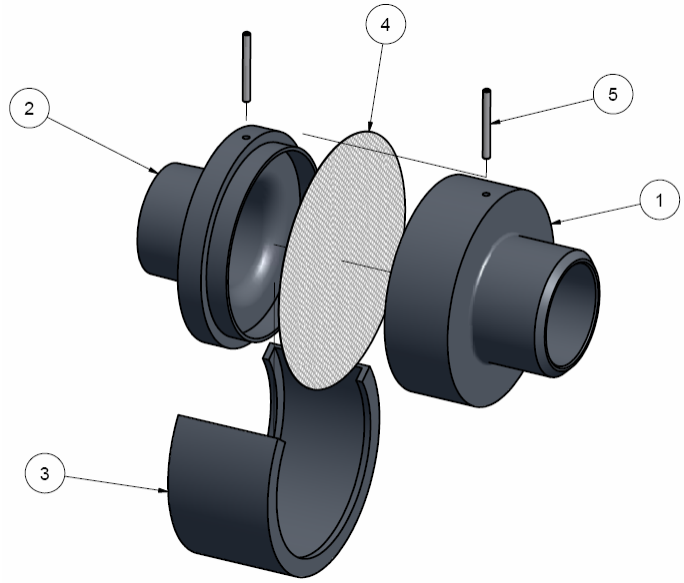


Figure 3.4-1 Flowmeter assembly.

Inside the Innocor a small flowmeter print is placed below the Single Board Computer. The print contains an amplifier of the differential pressure signal to a ±10 volt signal.

Differential pressure sensor:	163PC01D36, Honeywell
Amplifier:	AD620
Input range:	±5 “ H2O.
Output signal:	±10 volt
Filter:	Low pass @ 18.8 Hz

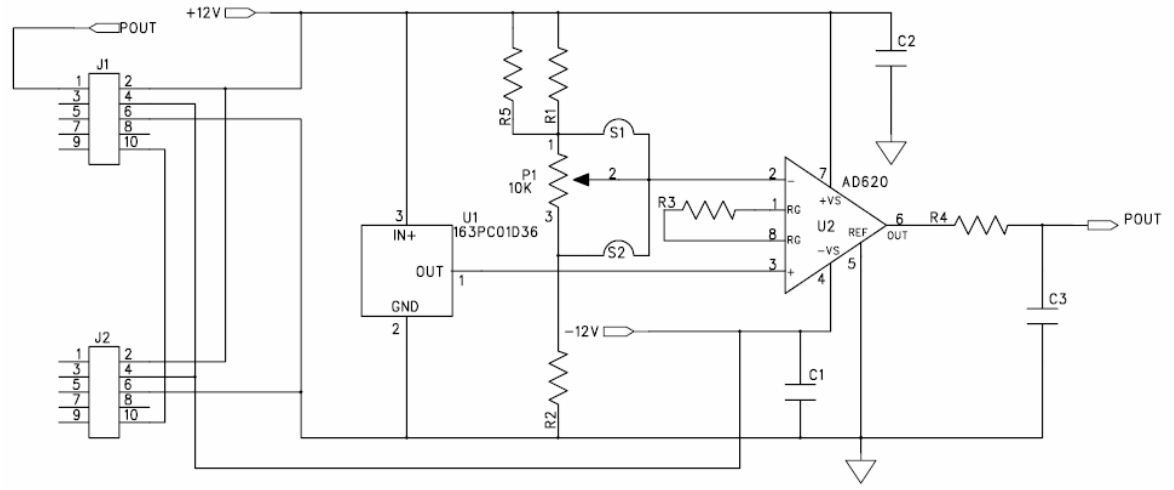


Figure 3.4-2 Electrical diagram of the BBB sensor electronics.

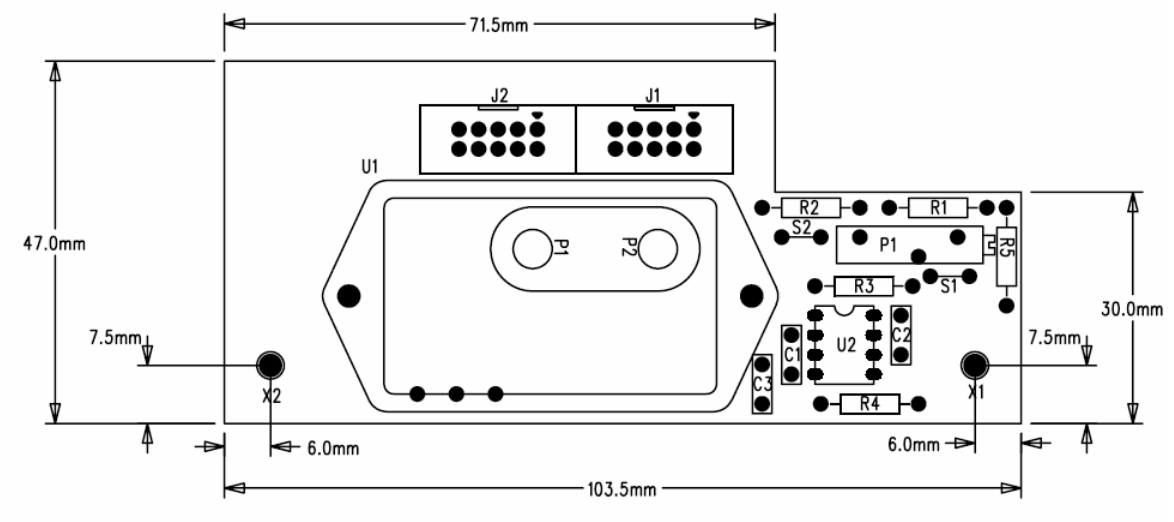


Figure 3.4-3 Electrical diagram of the BBB sensor electronics.

The flowmeter print is inserted on the 10 pin flat cable (containing analogue signals) from the I/F board to the PGA. I.e. the cable from the PGA is connected to the flowmeter print (J1), and a cable from the flowmeter print (J2) is connected to the I/F board. All lines in the cable from the PGA are transferred to the I/F board via the flowmeter print, except the MPP signal, which is replaced by the flow signal.

The output of the differential pressure sensor can be offset adjusted using the potentiometer P1. Note the output is temperature dependent and can drift approx. 100-200 mV during warm-up (2-4 hours). The Innocor software measures automatically the offset by connecting the 2 pressure ports (P1 & P2) using a valve on the IF board. As default the auto zero intervals are 1 minute.

The Innocor has a built-in standard factory flowmeter calibration table based on a multi stroke calibration (Yeh et al. 1982). It is recommended to make a daily calibration check of the flowmeter gain. The flow is calculated as:

Flow = Gain • Table(raw signal – offset)

Where

Raw signal =	the output of the differential pressure sensor in volt
Offset =	the offset of the differential pressure sensor found by auto zeroing
Gain =	the day to day gain factor, which should be in the range [0.9 – 1.1]. 2 gain factors are used – one for inspiration and one for expiration.

3.5 PULSE AND S_PO_2 MODULE

Oxygen saturation

Haemoglobin is a protein and the main component of red blood cells. Haemoglobin transports oxygen from the lungs, where oxygen tension (partial pressure of oxygen) PO_2 is high, to the tissues, where oxygen tension is low. Oxygen saturation, SO_2, is defined as the ratio of the amount of bound oxygen to the total oxygen capacity:

$$HbO_2 sat = \frac{HbO_2}{RHb + HbO_2}$$

where

HbO_2 is the concentration of oxyhaemoglobin and

RHb is the concentration of deoxyhaemoglobin.

If the haemoglobin molecule is bound to oxygen then one has oxy-haemoglobin or HbO_2. If the haemoglobin molecule is bound to carbon monoxide then one has carboxy-haemoglobin or HbCO. If the haemoglobin molecule is bound to nothing then one has deoxy-haemoglobin or RHb or reduced haemoglobin.

In healthy adults arterial oxygen saturation is approximately 97%. This depends on physiological parameters as well as on the oxygen partial pressure of the inspired air. In venous blood the oxygen saturation is approximately 75%.

Absorption of haemoglobin

Colour appears when some of the light shinning on or through a substance is absorbed. When haemoglobin picks up oxygen in the lungs, it changes from dusky bluish-red to bright red. Measuring the colour of blood, therefore, makes it possible to estimate how much of the haemoglobin in the blood is bluish and reduced, and how much is red and oxygenated. The light absorbed (or extinguished) by haemoglobin extends from red (wavelengths between 650 nm and 750 nm) to the infrared (900 nm to 1000 nm) region.

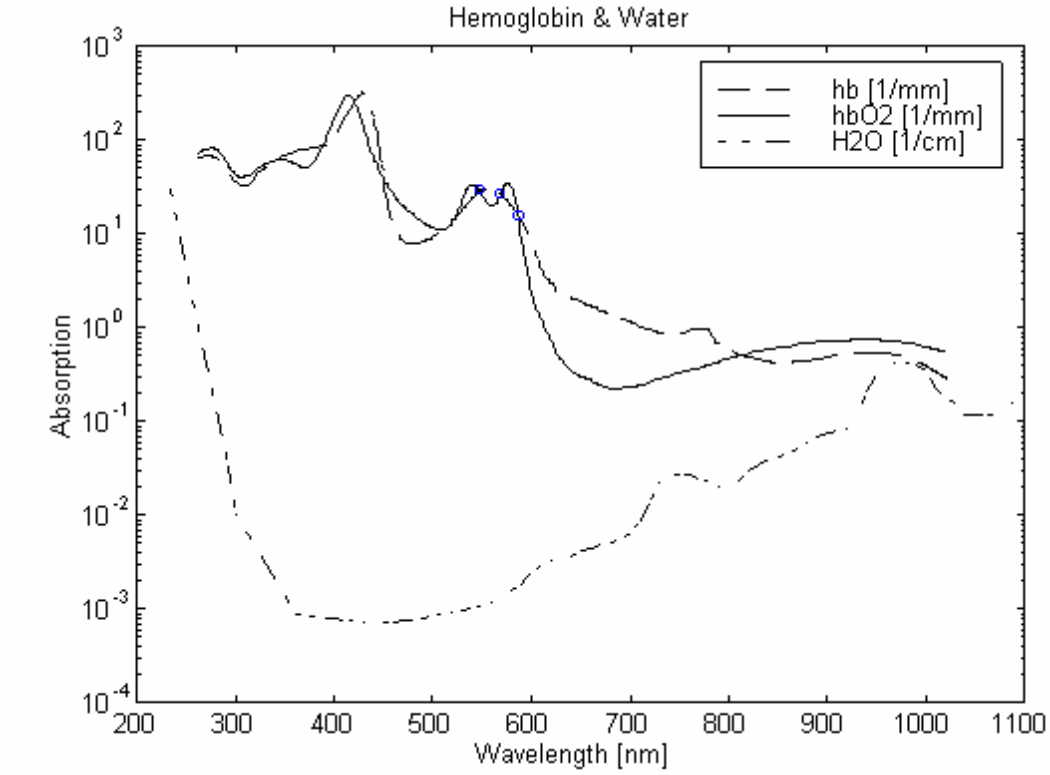


Figure 3.4-1 absorption measurements of haemoglobin.

To measure SO_2 non-invasively, the pulseoximeter shine light through the finger or earlobe. But then it measures a mixed sample of venous and arterial blood. To measure the arterial blood alone, the pulse oximeter technique is used which considers only the oscillating components of the optical signals. Complex fluid dynamic models describe pressure and blood flow in arteries. However we only need to consider the propagation of the pressure pulse in arteries which normally is sharply increasing during heart contraction, decreasing until the aorta valve is closed and can have a second peak afterwards when backflow to the heart stops
The pulseoximeter is mounted on top of the IF Board.

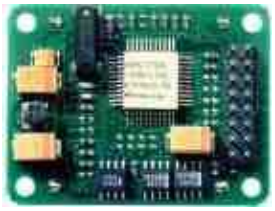


Figure 3.4-2 Pulse and SpO_2 module.

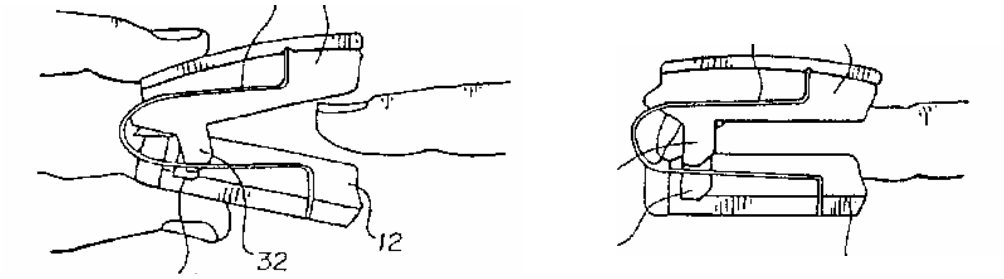


Figure 3.4-3 Pulseoximeter finger clip.

3.6 BLOOD PRESSURE MODULE

Figure 3.6-1 Blood pressure module.

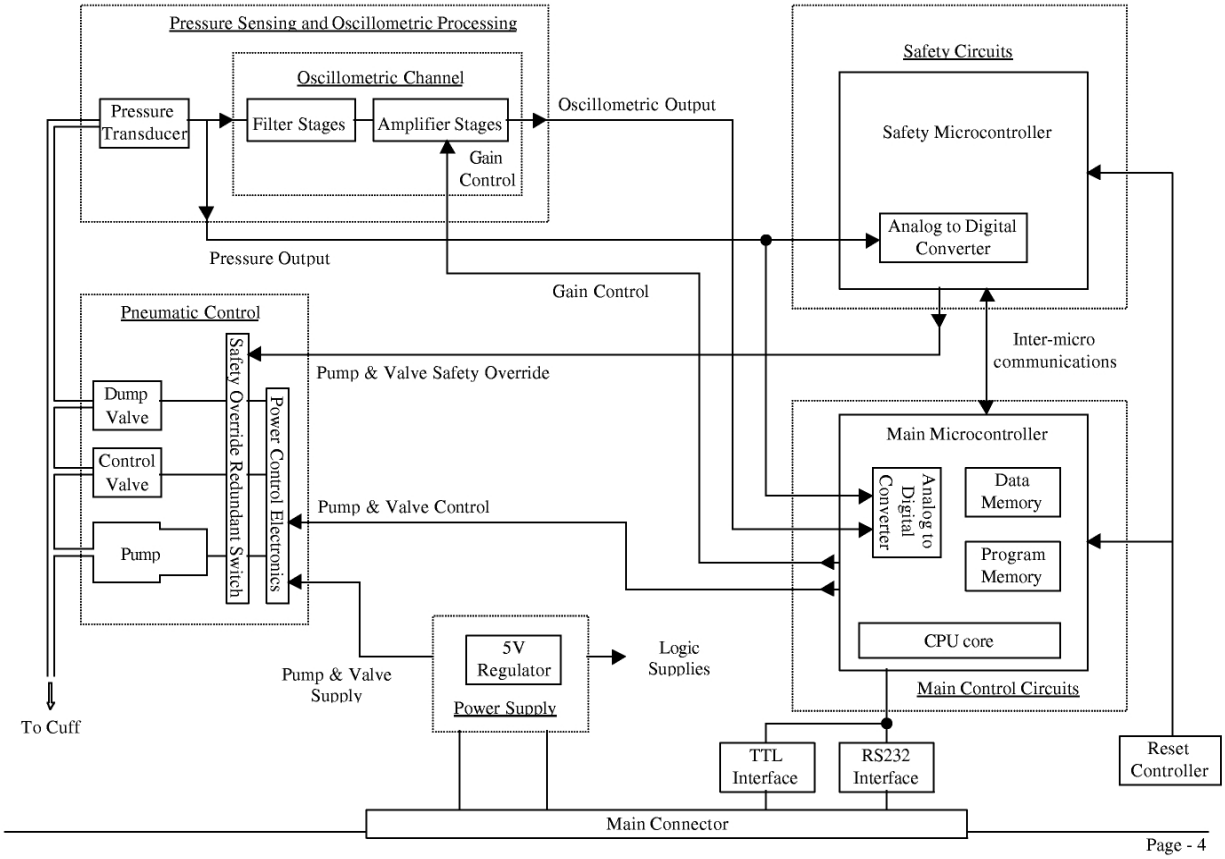


Figure 3.6-2 Simplified functional diagram of Blood pressure module.

3.6.1 Description of Operation

The major components and interconnections of the Advantage are shown in the Block Diagram. The pressure transducer converts the cuff pressure to an analogue output voltage, and also detects the small oscillometric waveforms resulting from the patient's arterial pulses. The oscillometric waveform is passed through a filter network (rejecting artefact and other noise) while being amplified. The amplifier gain setting is controlled by the main microprocessor; to compensate for differences in pulse volume and attenuation expected with different patients and hookups.

After digitisation of the oscillometric signal by the analogue to digital converter (ADC) contained in the main microprocessor, the signal is further filtered (using software filtering techniques) before being used by the main algorithm to determine the systolic and diastolic points in the waveform. Simultaneously, the cuff pressure is measured directly from the transducer output by a different channel of the ADC. By combining the information provided by the oscillometric waveform and the cuff pressure, the systolic and diastolic blood pressures are determined. Analysis of the oscillometric waveform also provides information on the pulse rate, which is stored in the microprocessor's nonvolatile memory, together with the blood pressure results.

Oscillometric method

Method wherein a cuff is placed on the limb, see figure 2.5.5-1, and the pressure in the cuff is increased until the blood flow in the artery is interrupted and then the pressure in the cuff is slowly reduced.
NOTE! During the inflation and deflation of the cuff small pressure changes (oscillations) occur in the cuff as a result of the arterial blood pressure pulses.
These oscillations, which first increase and then decrease, are detected and stored together with the corresponding cuff pressure values in the measurement system. With these stored values the systolic, diastolic and mean arterial blood pressure values can be mathematically derived using an appropriate algorithm.

3.6.2 Description of Safety

Operation of the pumps and valves is normally controlled by the main microprocessor, which will energise or de-energise the components as necessary to perform the blood pressure measurement as described above. However, the power control for the valves and pump contains an additional, redundant, backup switch. This backup switch is controlled by the safety microprocessor, which independently monitors the system pressure, the length of time that the system has been pressurised and other possible fault conditions within the system. Should the safety microprocessor detect any fault condition (e.g. an overpressure situation, if the system has become pressurised above the maximum limit), it will de-energise the redundant backup switch, cutting all power to the pump and valves. The valves are normally open devices, so in this situation they will both open, causing a fast dump of any pressure that may have been in the system at that time. The pump is obviously inhibited from further operation, as it is without any power.

Correct operation of the pressure transducer is monitored by a system of sanity limits implemented in both microprocessors, and by checking the pressure profile detected by the transducer when the pump is inflating. Other conditions and situations monitored that will cause readings to be aborted include calibration data corruption, power supply malfunction, low input voltage, leaky or blocked pneumatics and various other electronic faults. Additionally, both microprocessors perform a watchdog function over each other.

3.6.3 Calibration

Calibration data is held within the non-volatile memory of the main microprocessor. Integrity of this data is assured by a system of CRC error detection, redundant data tables and sanity limits. Calibration can only be performed using a set of special commands. There is also a hardware enable/disable jumper, which is enabled in Innocor.

3.6.4 Electronic

The power supply provides voltage step-up and regulation functions to drive the other electronic components. The pump and valves run directly from the input VPV voltage supply, there are software protections to detect low V logic and low VPV.
The complete electronic system is built on a single circuit board, eliminating internal interconnection systems and thus improving reliability. The unit is constructed with surface mount technology, with the exception of the pneumatic and mechanical components, further enhancing reliability and reducing size and weight.

The LK1 jumper must be installed during calibration.

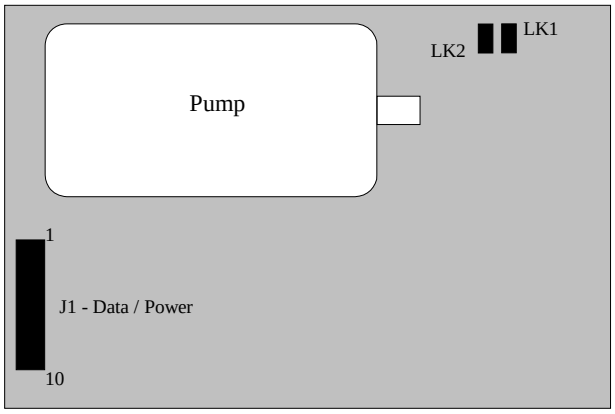


Figure 3.6.4-1 Print layout of Blood pressure module.

3.7 GAS DISTRIBUTION SYSTEM

3.7.1 Description

The Gas Distribution System (GDS) controls the pneumatics for the Respiratory Valve Unit (RVU) and the filling/evacuation of the rebreathing bag. The figure below shows the location of the main components in the GDS.

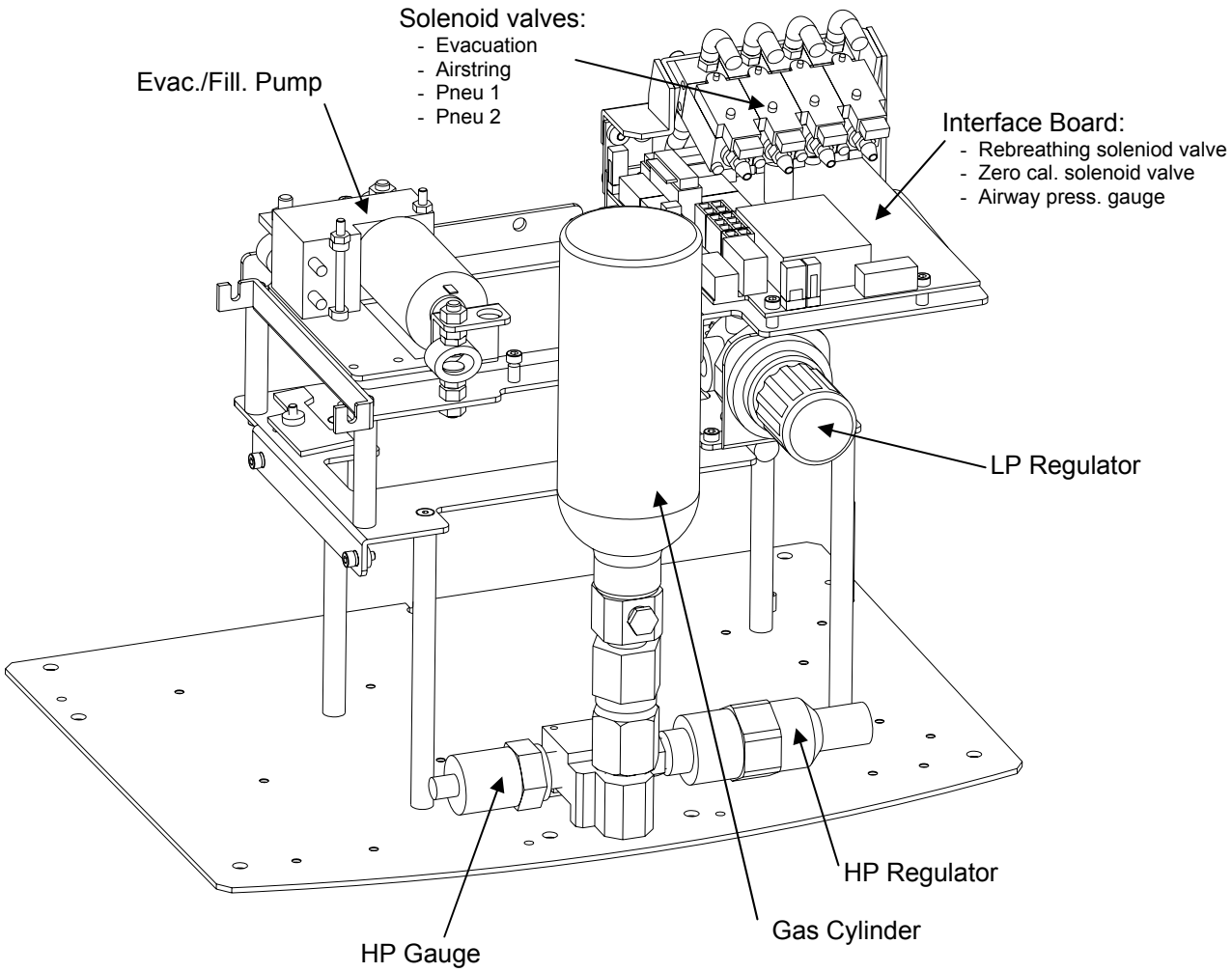


Figure 3.7.1-1 The Gas Distribution System with its main components.

3.7.2 The components in the GDS

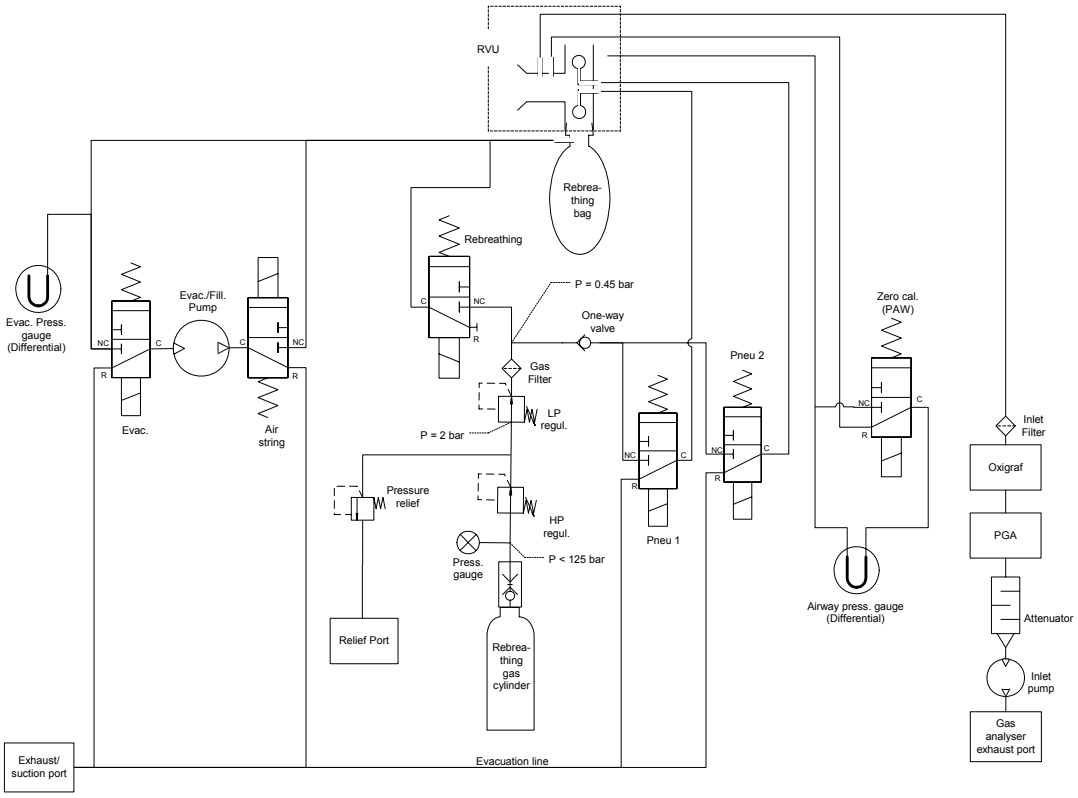


Figure 3.7.2-1 Gas Distribution System, plumbing diagram.
Port ID: C=Common, NC=Normally closed, R=Relief

The "evacuation"- and "air string" solenoid valves allow air to be filled into- and evacuated from the rebreathing bag. The "evacuation/filling pump" delivers the required airflow for the purpose.

The "evacuation pressure gauge" measures the pressure in the rebreathing bag. The signal is used to determine when the rebreathing bag has been completely emptied during an evacuation mode.

The "HP regulator" (High Pressure) and the "LP regulator" (Low Pressure) serve the purpose of regulating the highly varying gas cylinder pressure down to a constant working pressure at 0.45 bar.

The pressure relief valve ensures that pressure higher than 3.5 bar is not exposed to the low pressure side in case of failure in the HP regulator.

The "rebreathing" solenoid valve delivers the bolus gas for rebreathing bag gas mixture.

The "Pneu 1" and "Pneu 2" solenoid valves control the inflatable pneumatic elements in the RVU (Respiratory Valve Unit).

The "one-way valve" prevents air in the inflated pneumatic elements (in the RVU) from escaping into the rebreathing bag during a bolus filling.

The "airway pressure gauge" measures the mouthpiece pressure. Among several applications this signal is used for the timing of the patient breath with the position of the RVU. The gauge is offset calibrated by activating the "zero calibration" solenoid valve. The BBB option contains an extra (and more precise) differential pressure transducer in parallel with the "airway pressure gauge".

The offset of the differential pressure transducer is also calibrated by the "zero calibration" solenoid valve.
The "Gas sampling system" can be studied in detail in section 3.1

3.7.3 The operational modes

A detailed description of the solenoid valve positions for the various modes is given through a series of figures. The highlighted components mean that they are activated.

The GDS have four different operational modes:

- GDS in ”emptying bag mode” (figure 3.7.3-1). The evacuation/filling pump is running, and the "pneu 1" solenoid valve is activated. The rebreathing bag is hereby emptied. The "evacuation pressure gauge" is detecting when the bag is completely empty. The evacuation/filling pump is then stopped.
- GDS in "Bolus filling mode" (figure 3.7.3-2). The "rebreathing" and the "pneu 1" solenoid valves are activated. Bolus gas flows from the gas cylinder into the rebreathing bag.
- GDS in "Air filling mode" (figure 3.7.3-3). The evacuation/filling pump is running. The "evacuation" and "air string" solenoid valves are activated allowing ambient air to be filled into the rebreathing bag. The "pneu 1" solenoid valve is also activated during the session. Prior to the shift into "rebreathing mode" (see below), the "airway pressure gauge" is offset calibrated by activating the "zero cal." solenoid valve.
- GDS in "Rebreathing mode" (figure 3.7.3-4). The "pneu 2" solenoid valve is activated. Subject is breathing into the rebreathing bag. The gas composition (mouthpiece) is analysed in the gas analyser assembly.

During all the four modes the "Gas analyser assembly" is pumping air from the RVU through the Gas analyser and out the "Gas analyser exhaust port".

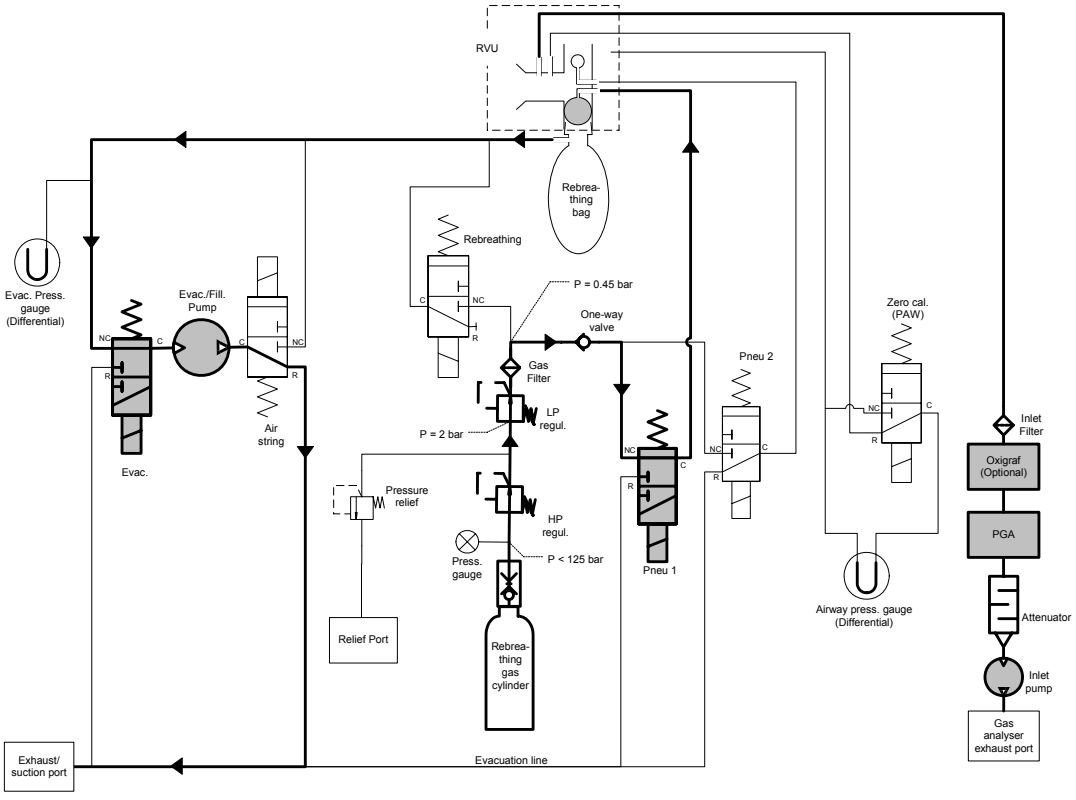


Figure 3.7.3-1 GDS in " emptying bag mode".

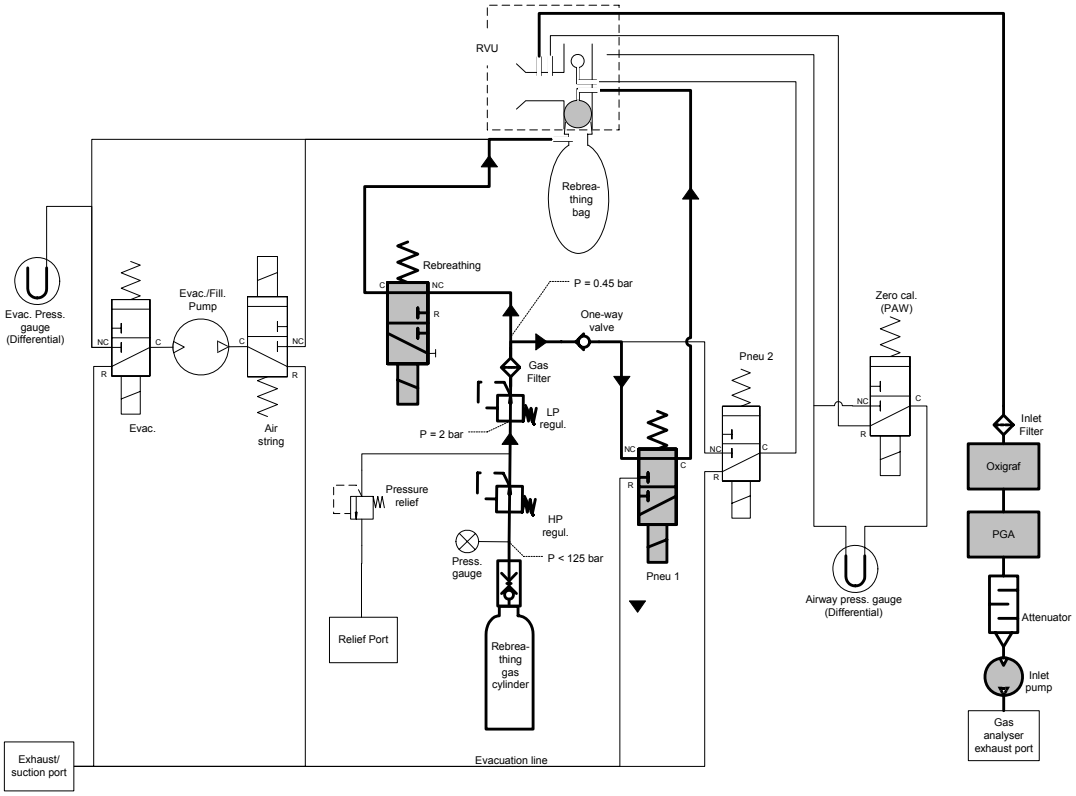


Figure 3.7.3-2 GDS in "filling bolus mode".

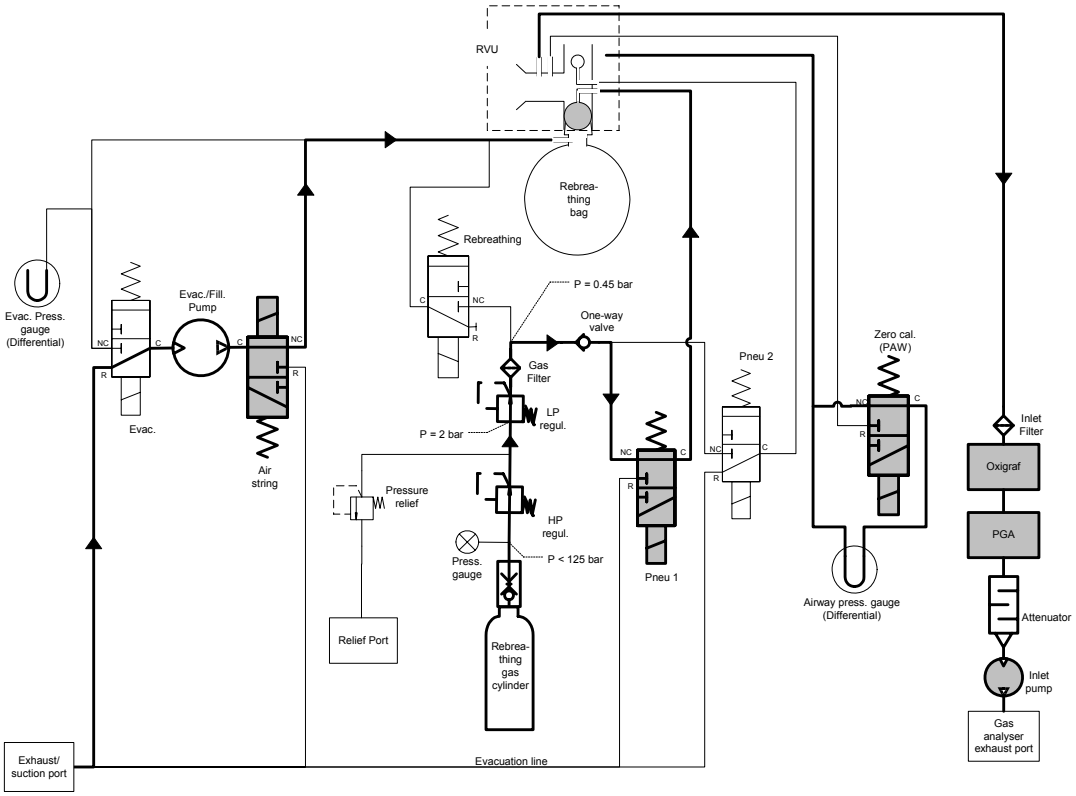


Figure 3.7.3-3 GDS in "filling air mode".

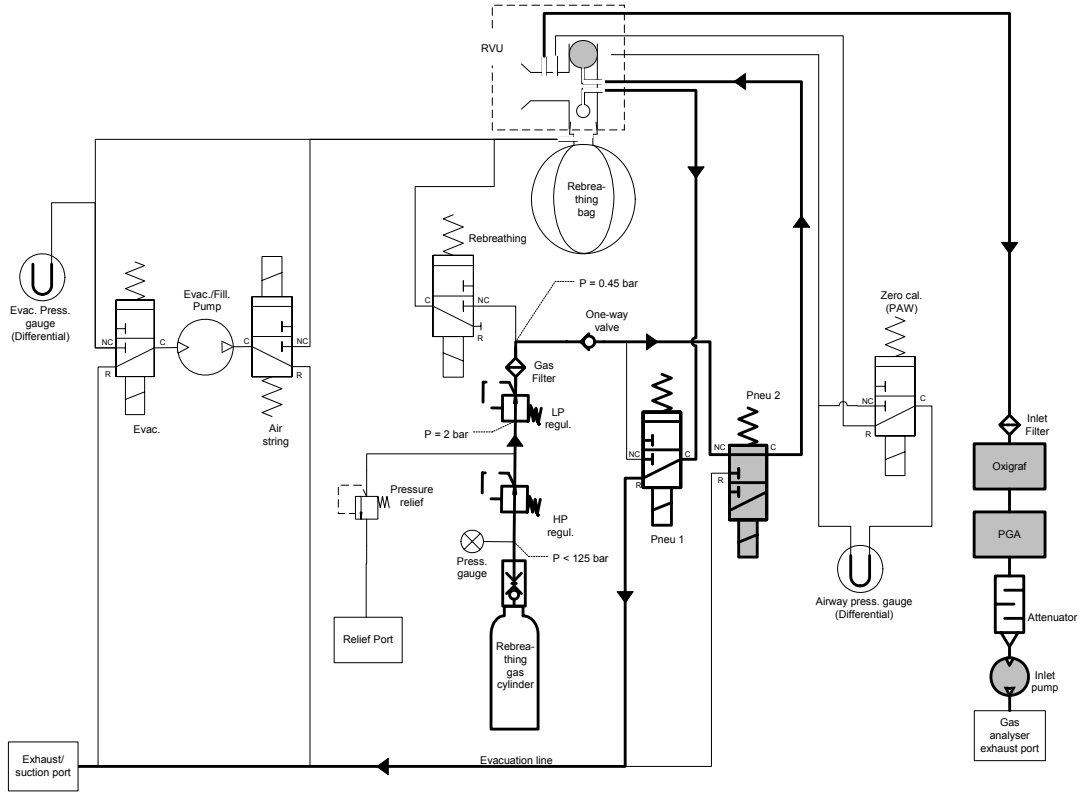


Figure 3.7.3-4 GDS in "rebreathing mode".

3.7.4 Specifications, Gas Distribution System

General specifications

Description: .....High Pressure oxygen compliant system
Max leak rate:.....< 5 ml/hour @ standby
..... < 50 ml/hour @ operation

Rebreathing Gas Cylinder

Description: ..... High pressure aluminium cylinder with relief valve
Water capacity:.....0.15 litre
Materials:.....Aluminium (6061-T6), Brass, Stainless steel, Viton
Cleaning: .....Cleaned for oxygen service
Max service pressure: ..... 124 bar
Min test pressure: ..... 186 bar
Max leak rate: ..... $<10^{-4}$ litre/hour

The Gas Cylinders are manufactured and inspected in accordance with U.S. Department of Transportation (DOT), 3AL and Transport Canada (TC) 3ALM requirements and Arbejdstilsynet, Denmark (π 0030).

Make sure that both the male and female gas connections are kept clean and free from oil, grease and hydrocarbons before screwing the cylinder onto the device. Use no lubricant. Use only cleaning agents that do not leave organic residues.

NOTE: To reduce friction gas cylinders are supplied with a small amount of a special lubricant for oxygen service on the threaded part (Krytox, GPL 205). Do not remove this lubricant.

High-pressure Regulator

Description: .....Non-relieving high pressure regulator with o-ring sealed piston
Inlet pressure:..... 5 to 206 bar
Flow pressure:..... 2 bar
Flow rate:.....8.0 slpm +/- 1.0 slpm @ 62 bar
Materials:..... Brass Ni-plated body, bonnet, brass piston, Viton o-ring seal, PCTFE seat
Cleaning: .....Cleaned for oxygen service

Low-pressure Regulator

Description: ..... Non-relieving, low-pressure regulator with membrane
Inlet pressure: ..... 1 to 20 bar
Flow pressure:.....Factory preset at 0.45 bar (adjustable between 0.1 to 0.7 bar)
Flow rate:..... n/a
Materials: ... Zinc body, acetal bonnet, brass/nitrile valve, acetal valve seat, nitrile elastomere

High-pressure gauge

Description: .....Piezo resistive silicon transducer
Pressure range:.....0-175 bar
Long term stability (1 year): ..... +/- 0.25% FS
Burst pressure: .....>875 bar

Solenoid valves (Evacuation, Rebreathing, Pneu 1, Pneu 2)

Description: .....3/2 solenoid valve with manual override and LED
Orifice: ..... 1.6 mm
Max working pressure: .....3.5 bar
Power consumption: .....1.2 watt
Response time: ..... <3ms

Solenoid valves (Air string soleniod valve, Zero cal. solenoid valve)

Description: ..... 3/2 solenoid valve
Orifice: ..... n/a
Max working pressure: .....2.0 bar
Flow:.....10 litre/min @2.0 bar
Power consumption: .....1.0 watt
Response time: ..... <20ms

Evacuation/filling pump

Description: ..... Piston pump
Free flow: .....4.3 litre/min.
Max intermittend pressure:..... 2.0 bar
Max vacuum:.....-580 mbar
Power consumption: .....6 watt

Inlet pump

Description: ..... Membrane pump
Free flow:.....0.85 litre/min.
Max intermittend pressure:..... n/a
Max vacuum:..... n/a
Power consumption: .....0.7 watt

3.8 MAIN INTERFACE BOARD

The function of the “I/F Board” is to make the interface to different transducers via the “Photoacoustic Gas Analyser” (PGA) from the “Single Board Computer” (SBC), see figure 2.6-1.
The “I/F Board” is also managing the distribution of the three different voltages.
The interface between the “SBC” and “PGA” is a standard RS-232 connection.
The interface between the “PGA” and “I/F Board” is a combination of analogue and digital lines.

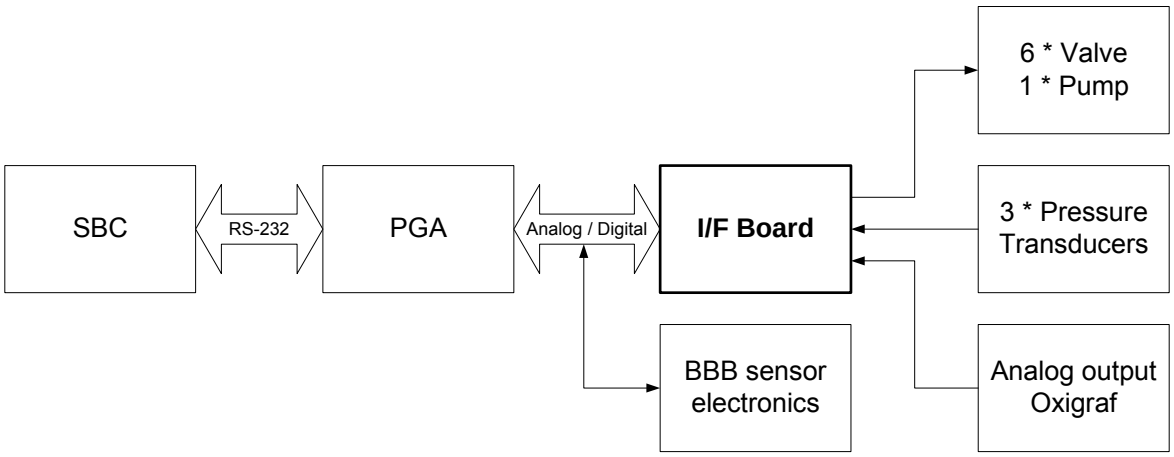


Figure 3.8-1 Block diagram of interface for the I/F Board.

3.8.1 Power supply

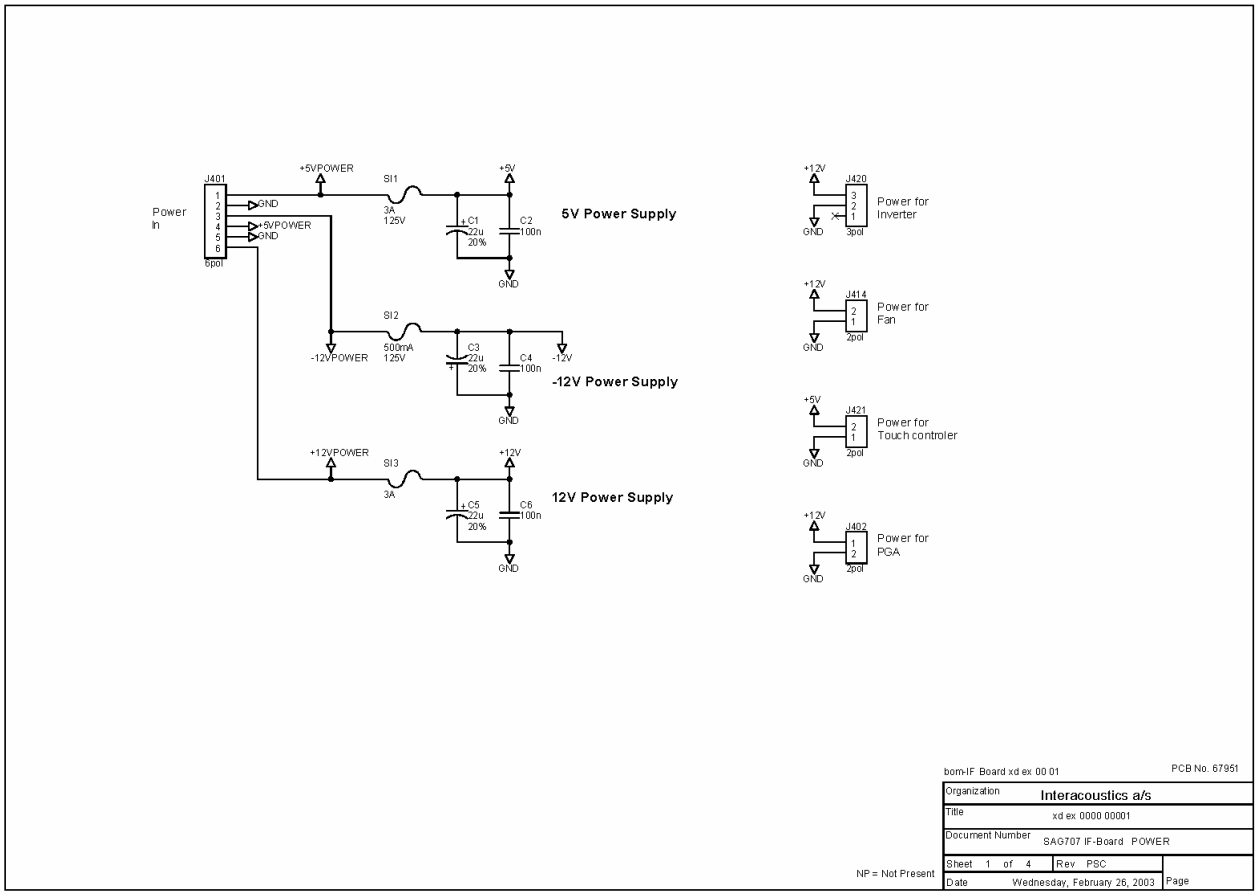


Figure 3.8.1-1 Power supply.

The “I/F Board” is powered by the systems main power supply. The “I/F Board” distributes the different supplies to the subsystems. The power supply is a 60 Watt (VLT60-3000), which offers the following three supplies:

Voltage [V]	Current [A]
12	3
-12	0.5
5	8

Table 3.8.1-2 Power supply output.

The 3 supplies are used as indicated in the table below:

Subsystem	5 V	12 V	-12 V
Touch controller	x		
Inverter		x	
Fan		x	
PGA		x	
SBC	x	x	x
Oxigraf	x	x	x
NIBP	x	x	x
Pulse Oximeter	x	x	x

Table 3.8.1-3 The subsystems use of power.

3.8.2 Valve control

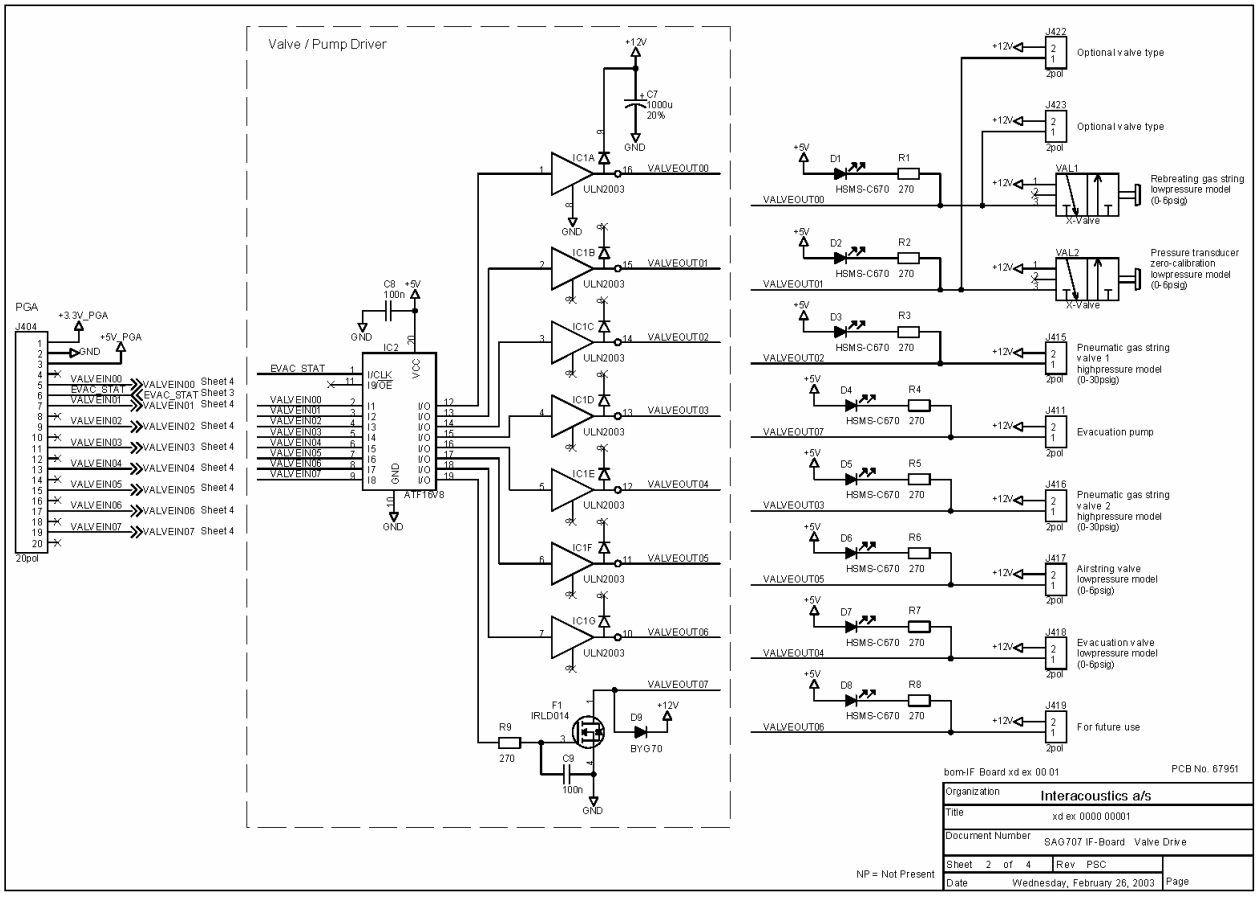


Figure 3.8.2-1 Valve control.

The PGA via a PAL circuit with the following coding controls the valves and pumps:

D0	D1	D2	D3	D4	D5,D6,D7		Pneu 1	Pneu 2	Reb	Air	Evc	Paw	Pump	Spare	Comments
0	0	0	0	0	x		0	0	0	0	0	0	0	0	All valves off
1	0	0	0	0	x		1	0	0	0	0	0	0	0	Normal breathing
0	1	0	0	0	x		0	1	0	0	0	0	0	0	Rebreathing
1	1	0	0	0	x		0	0	1	0	0	0	0	0	Valve test
0	0	1	0	0	x		0	0	0	1	0	0	0	0	Valve test
1	0	1	0	0	x		0	0	0	0	1	0	0	0	Valve test
0	1	1	0	0	x		0	0	0	0	0	1	0	0	Valve test
1	1	1	0	0	x		0	0	0	0	0	0	1	0	Valve test
0	0	0	1	0	x		0	0	0	0	0	0	0	1	Valve test
1	0	0	1	0	x		1	1	0	0	0	0	0	0	Respiratory valve blocked
0	1	0	1	0	x		1	0	0	0	1	1	1	0	Bag evacuation
							1	0	0	0	1	1	0	0	Bag evacuation, pump off & bag empty
1	1	0	1	0	x		1	0	1	0	0	1	0	0	Bag filling with bolus gas
0	0	1	1	0	x		1	0	0	1	0	1	1	0	Bag filling with air
1	0	1	1	0	x		1	0	1	1	0	1	1	0	Bag filling with bolus and air
0	1	1	1	0	x		1	0	0	0	0	1	0	0	Paw pressure zeroing
1	1	1	1	0	x		0	1	1	0	0	0	0	0	Bolus gas injection during rebreathing
x	x	x	x	1	x		x	x	x	x	x	x	x	x	Future use

Table 3.8.2-1 PAL circuit (IC2) coding.

3.8.3 Sensor Interface

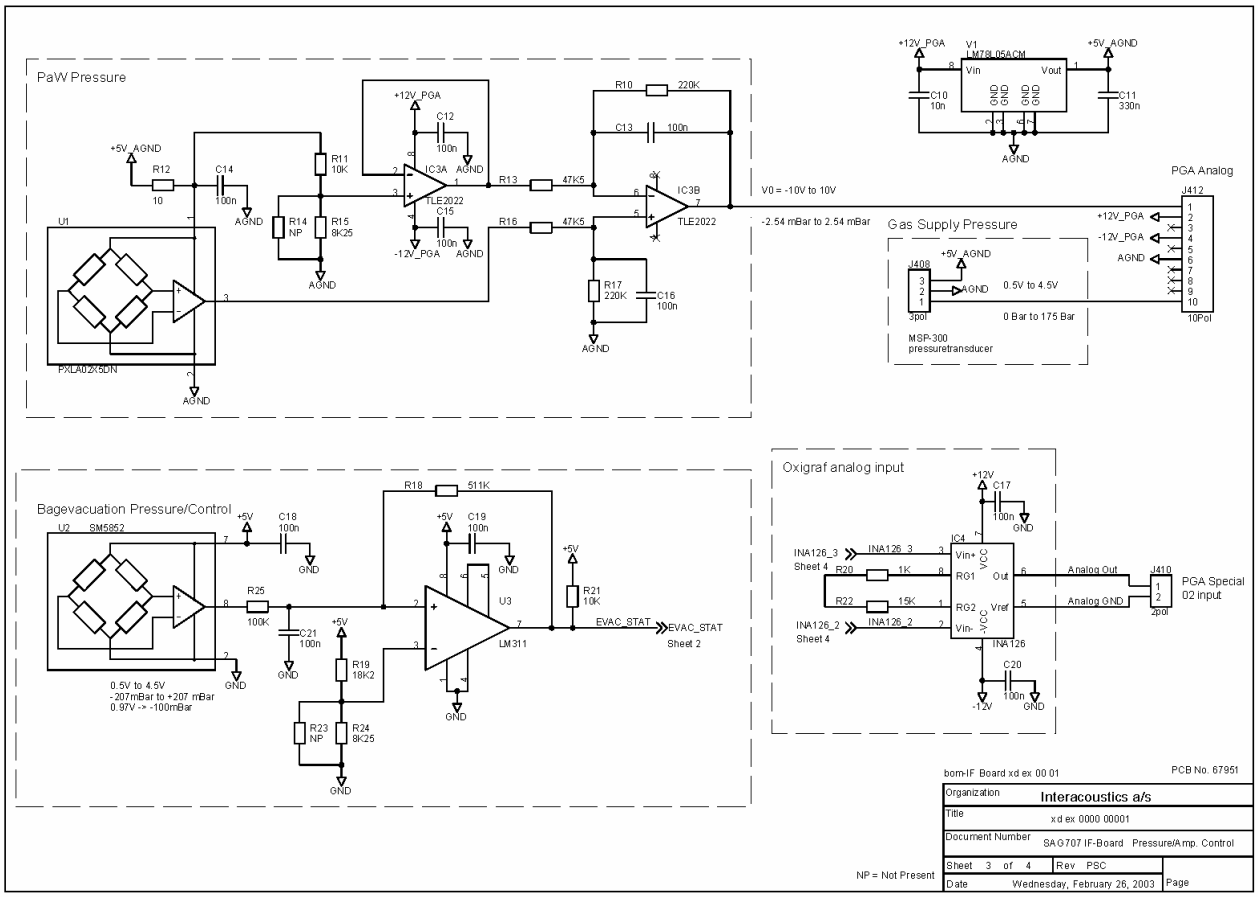


Figure 3.8.3-1 Sensor interface.

3.8.3.1 Airway pressure

The airway pressure (PaW) is the pressure, over- and underpressure that arise when a patient breathes in the Respiratory Valve Unit (RVU). The pressure is measured immediately after the mouth in the RVU, and is used to trigger the opening of the valve at the shift from expiration to inspiration.

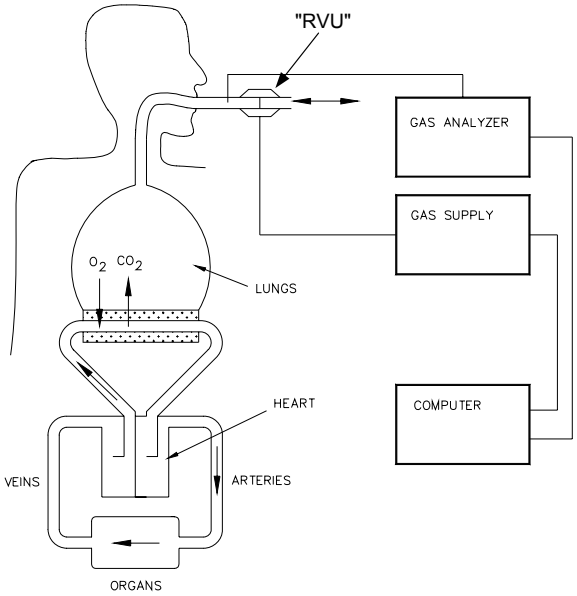


Figure 3.8.3.1-1 Measuring of airway pressure.

3.8.3.2 Bag evacuation pressure

The “Bag Evacuation Pressure” is the pressure that arises when the evacuation pump (EVAC Pump) empties the rebreathing bag. The pressure is used to detect when the “Rebreathing Bag” is empty. When this is the case the evacuation pump is automatically turned off.

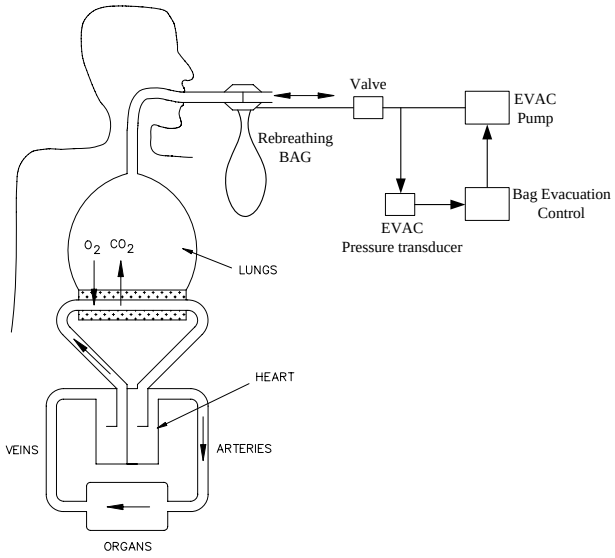


Figure 3.8.3.2-1 Measuring of bag evacuation pressure.

3.8.3.3 Oxigraf converter

The “Oxigraf analogue input” circuit amplifies the oxygen signal from the oxigraf with a factor 10 (from 0-1 V to 0-10 V corresponding to 0-100% O_2). The circuit converts also the signal from a differential output to a single ended input on the PGA.

3.8.3.4 Gas Supply Pressure

The Gas supply pressure sensor gives a 0.5-4.5 V output for an input in the range 0-175 bar.

3.8.4 External interfaces / Buzzer

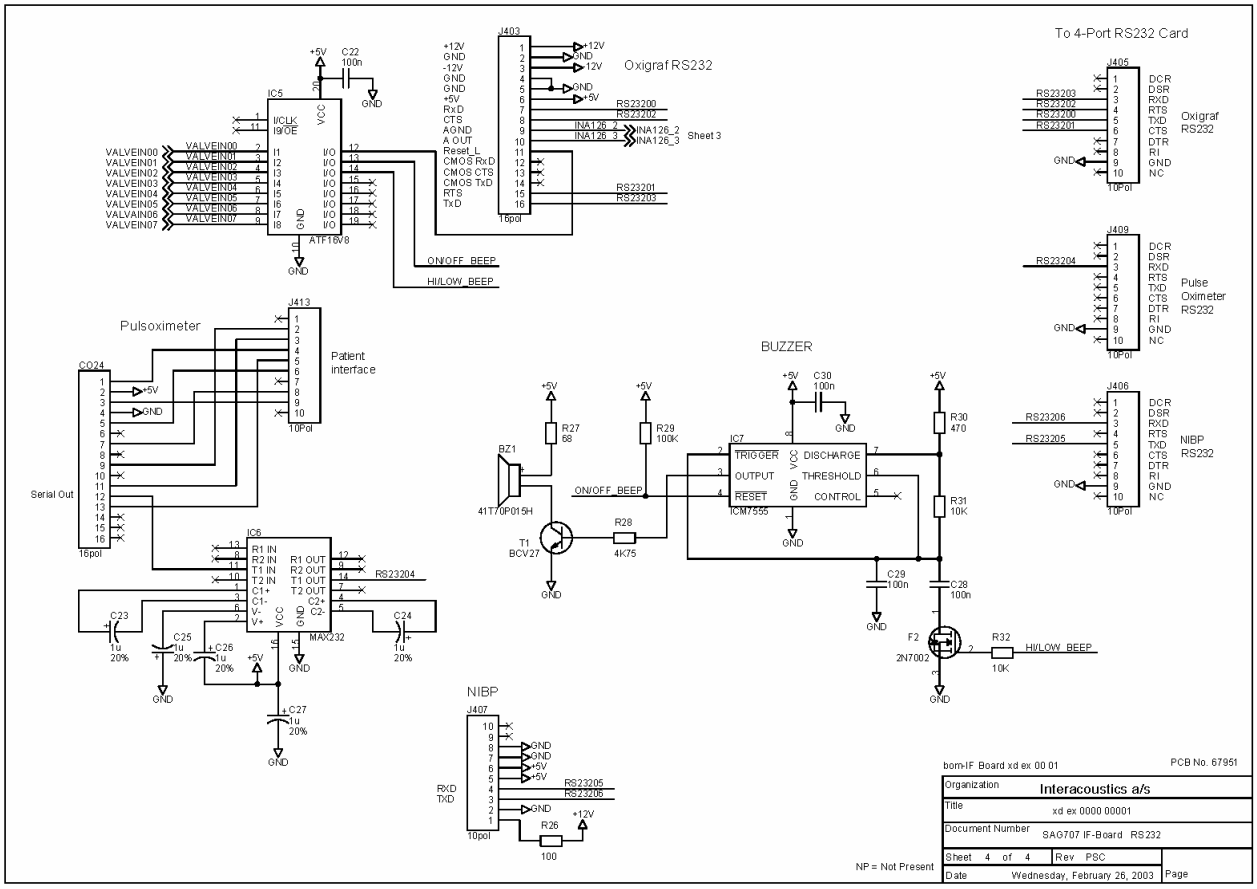


Figure 3.8.4-1 External interfaces/Buzzer.

The PGA via a PAL circuit with the following coding controls the buzzer:

D0,D1,D2,D3,D4	D5	D6	D7		Reset_L	Beep_On	Beep_Low	Comments
x	0	x	0		1	0	0	Beep off
x	1	x	0		1	1	0	Beep on, high frequency (approx. 600 Hz)
x	0	x	1		1	0	1	Beep off
x	1	x	1		1	1	1	Beep on, low frequency (approx. 300 Hz)

Table 3.8.4-1. PAL circuit (IC5) coding.

The IC6 converts the serial signal of the pulseoximeter from TTL to RS232

3.8.5 I/F Board electrical Interconnections

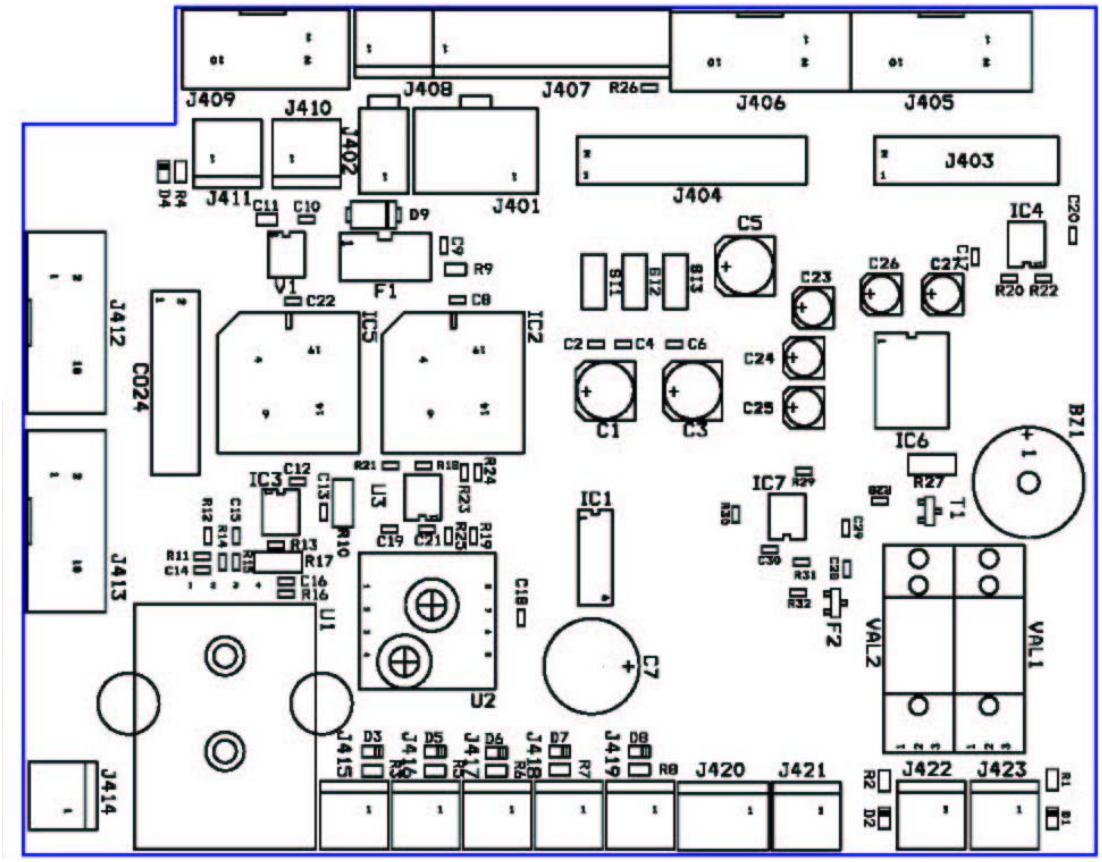


Figure 3.8.5-1 I/F Board electrical interconnections

Connector	Name	Connected to
J401	Power IN	Power supply
J402	Power PGA	PGA
J403	Oxigraf	Oxigraf
J404	PGA Aux	PGA
J405	Oxigraf RS232	SBC
J406	NIBP RS232	SBC
J407	NIBP Power	NIBP PCB
J408	High Pressure Gas Supply Sensor	Gas Supply Sensor
J409	Pulse Oximeter RS232	SBC
J410	Analog Oxigraf	PGA
J411	Gas Fill/Evac Pump	Gas Fill/Evac Pump
J412	PGA Analogue	PGA or BBB sensor electonics
J413	Patient Interface Panel	Patient Interface Panel
J414	Fan Power	Fan
J415	Pneu 1 Valve	Pneu 1 Valve
J416	Pneu 2 Valve	Pneu 2 Valve
J417	Air String Valve	Air String Valve
J418	Evacuation Valve	Evacuation Valve
J419	Future Use Valve	Not connected
J420	Inverter PCB	Inverter PCB
J421	Touch Screen Power	Touch Screen PCB
J422	Rebreathing Valve optional type	Not connected
J423	PaW Valve optional type	Not connected

Circuit	Name
IC5	Control PAL
IC2	Valve PAL
U1	MPP pressure sensor
U2	Evacuation pressure sensor
VAL1	Rebreathing valve
VAL2	MPP zero cal. (PaW)

3.9 COMPUTER

3.9.1 CPU module

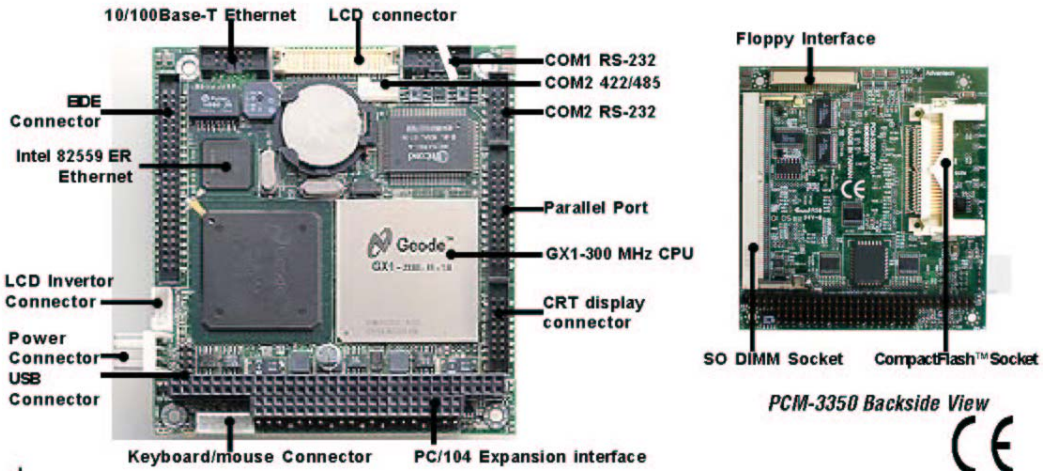


Figure 3.9.1-1 CPU module.

The **10/100Base-T Ethernet** and **USB connector** is connected to the data interface panel on the rear side of the Innocor. **LCD connector** and **LCD Inverter Connector** is connected to the front panel (Display) of the Innocor. **COM1 RS-232** is connected to the PGA. The **EIDE Connector** is connected to the hard disk, and the **Power Connector** is connected directly to the power supply.

The CPU module is an Advantech PCM-3350 board.

Specifications	Used in Innocor
CPU: Embedded low power NS Geode GX1-300 MHz processor, fanless	Used
BIOS: AWARD 256 KB flash memory	Used
System memory: 128 MB SDRAM	Used
Enhanced IDE interface: supports up to 2 EIDE devices.	1 used
FDD interface: support up to 2 FDDs	Not used
Serial ports: 1 serial RS-232 port, 1 serial RS-323/422/485 port	1 used for PGA
Parallel port: 1 parallel port, supports SPP/EPP/ECP	Not used
Infrared port: Shared with COM 2	Not used
Keyboard/mouse connector: Mini-DIN connector supports standard PS/2 keyboard and mouse	Not used
Watchdog timer: Software enable/disable	Not used
VGA:	
Chipset: NS CS5530	Used
Display memory: 1-4MB	4 MB used
Display type: Supports CRT and LCD	LCD used
Flat-panel display mode: up to 1024x768 @ 18 bpp	800x600 used
CRT display mode: up to 1024x768 @ 24 bpp	Not used
Ethernet:	
Chipset: Intel 82559 ER	Used
Ethernet interface: PCI 10/100 Mbps Ethernet (IEEE 802.3 U protocol compatible)	Used
USB: 2xUSB 1.1.	Used

3.9.1.1 BIOS Setup

Below is the complete bios set-up for the Award BIOS setup of the PCM-3350.

* The setting has been changed from the default values.

Standard CMOS setup

Hard Disks	Type	Size	Cyls	Head	Precomp	Landz	Sector	Mode
Prim. master	User	0	0	0	0	0	0	AUTO
Prim. Slave Sec Master Sec. Slave	None	0	0	0	0	0	0	---

Drive A : 1.44M 3.5 in
Drive B : None

Video : EGA/VGA
Halt On **: All, But Disk/Key ***

Bios features setup

Virus warning	Disabled
CPU Internal Cache	Enabled
Quick Power On Self Test	Enabled
Boot From LAN First	Disabled
Boot Sequence	C,A,SCSI
Swap Floppy Drive	Disabled
Boot Up Floppy Seek	**Disabled***
Boot Up NumLock Status	On
Boot Up System Speed	High
Gate A20 Option	Fast
Memory Parity Check	Enabled
Typematic Rate Setting	Disabled
Typematic Rate (Chars/sec)	6
Typematic Delay (Msec)	250
Security Option	Setup
PCI/VGA Palette Snoop	Disabled
OS select For DRAM > 64MB	Non-OS2
Report No FDD For WIN 95	Yes

Video BIOS Shadow	Enabled
C8000-CBFFF Shadow	Disabled
CC000-CFFFF Shadow	Disabled
D0000-D3FFF Shadow	Disabled
D4000-D7FFF Shadow	Disabled
D8000-DBFFF Shadow	Disabled
DC000-DBFFF Shadow	Disabled

Chipset features setup

SDRAM CAS latency Time	3 T
SDRAM Clock Ratio Div By	4*
16-bit I/O Recovery (CLK)	5
8-bit I/O Recovery (CLK)	5
USB Controller	Enabled
USB Legacy Support	**Enabled ***

Power Management Setup

Power Management	Disabled
Standby Mode	Disabled
HDD Power Down	Disabled
MODEN Use IRQ	NA
Throttle Duty Cycle	33.3 %

IRQ1 (Keyboard)	ON
IRQ3 (COM 2)	OFF
IRQ4 (COM 1)	OFF
IRQ5 (LPT 2)	OFF
IRQ6 (Floppy Disk)	OFF
IRQ7 (LPT 1)	OFF
IRQ9 (IRQ2 Redir)	OFF
IRQ10 (Reserved)	OFF
IRQ11 (Reserved)	OFF
IRQ12 (PS/2 Mouse)	OFF
IRQ13 (Coprocessor)	OFF
IRQ14 (Hard Disk)	OFF
IRQ15 (Reserved)	OFF

PNP/PCI Configuration

PNP OS Installed	No
Resources controlled by	Auto
Reset Configuration	Disabled

PCI IRQ actived By	Level

Integrated peripherals

IDE HDD Block Mode	Enabled	Onboard Parallel Port	378 / IRQ7
Primary IDE Channel	Enabled	Parallel Port Mode	ECP + EPP
Master Drive PIO Mode	Auto	ECP Mode Use DMA	3
Slave Drive PIO Mode	Auto	EPP Mode Select	EPP1.9
IDE Primary Master UDMA	Auto	Multiple Monitor Support	No Onboard
IDE Primary Slave UDMA	Auto	Video Memory size	**2.5 M ***
IDE Secondary Master UDMA	Auto	Flat Panel Status	Enabled
Onboard Speaker	Enabled	Flat Panel Resolution	**800x600 ***
Onboard PCI Lan Chip	Enabled		
Keyboard input clock	8 MHz		
Onboard FDC Controller	Enabled		
Onboard Serial Port 1	3F8/IRQ4		
Onboard Serial Port 2	2F8/IRQ3		
Serial Port 2 Mode	RS232		
Onboard IR Controller	Disabled		

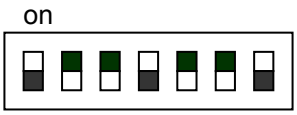
Password Setting: No password must be used !!!

3.9.2 4xserial module

The 4 port serial board is an Advantech PCM-3641 (PC/104).

SW1: Base address

Dip	Description	Setting
1..6	A3..A8 Base address = 200(A9) + 8(A3) + 40(A6) = 248	011011
7	Pin 7 = MODE0 = off = enhanced mode	1



SW2: Vector address

Dip	Description	Setting
1..5	Interrupt status register: = 280H = A4..A8	11101
6	Shared IRQ mode, MODE 1	1
7	Speed = OFF = Normal Speed Mode	0

IRQ Only one jumper at IRQ 9 in JP1
JP11 Windows 95/98/NT = 2-3 connected

Com Port	I/0 Address	Connected to
3	248	Touch Screen
4	250	Oxigraf
5	258	NIBP
6	260	Pulseoximeter

3.9.3 LCD

The LCD is a 12.1" Colour TFT LCD display with a SVGA resolution (800x600 pixels).
The LCD is controlled directly from the computer module. The backlight inverter PCB is powered from the I/F Board and is always on. See figure 2.6-1.

3.9.4 Touch

The touch screen is a high-resolution resistive type.

Jumper settings:

11	10	9	8	7	6	5	4	3	2	1	0
---		---			---		---		---		

The touch is controlled via the serial port 3 on the “4 port serial board” and powered from the I/F Board. See figure 2.6-1.

3.9.5 Hard disk

The hard disk is a 2.5” with a capacity of 10 GB or more.
No jumpers are installed corresponding to cable select.

4 MAINTENANCE

4.1 CALIBRATION CONCEPT

4.1.1 User calibration

a) The oxygen sensor may need 1-point calibration on a regular basis by the user, e.g. once a month. No tools are necessary as air is used for the adjustment. See section 4.3.2.

Without Breath-by-Breath:

b) The airway pressure sensor is automatically calibrated for zero-point as part of the bag preparation for each rebreathing test.

With Breath-by-Breath:

c) The flowmeter sensor is automatically calibrated for zero point on a regularly basis – as part of the bag preparation for each rebreathing test and by default every 1 minute during Breath-by-Breath measurements.

d) The flowmeter gain should be checked every day, and when the flowmeter screen has been changed. See section 4.4.1.

e) The flow-gas delay should be checked every day, and when the gas sample line has been changed. During an exercise test the flow-gas delay is automatically adjusted as default, when the exercise level is above a certain level (typical 1/3 of max load). See section 4.5.

4.1.2 Calibration / check by distributors

In accordance with the Instructions for Use it is recommended that the manufacturer or his representative perform a number of calibrations or calibration checks periodically on a 6-12 months basis. In order for the distributor to be authorised to do calibration and checkout, the Innocor service program and special procedures must be explained to him by an Innovision service engineer/technician. In addition to the Innocor service program the following tools are necessary to do the calibrations (available as a service kit from Innovision):

a) Low pressure regulator output pressure: Pressure sensor. See section 4.2.1.

b) Bolus filling flow rate: A 1-litre calibration syringe and a rebreathing bag. See section 4.2.3.

c) Air filling flow rate: A 1-litre calibration syringe and a rebreathing bag. See section 4.2.4.

d) Oxygen sensor: A gas mixture with 50% O_2 (or pure oxygen) supplied from a calibration gas bottle with constant flow regulator and a T-piece plus air for periodical 2-point calibration. See section 4.3.2.

e) Photo acoustic analyser: A gas mixture with 50% O_2, 1% N_2O, 0.2% SF_6, 5% CO_2, bal. N_2 supplied from a calibration gas bottle with constant flow regulator and a T-piece for periodical check or gain calibration. In the unlikely event that major deviations from the expected readings are found the device must be returned to Innovision for multi-point manufacturer calibration. See section 4.3.3.

f) Gas pressure sensor: Zero-point adjustment requiring no tools (bottle unscrewed). See section 4.6.

g) Flow: Gain calibration of the flowmeter using a 1 or 3-litre calibration syringe. If major deviations are found (>10%) a new calibration of the flow linearization table shall be performed using a 3-litre calibration syringe. See section 4.4.1 & 4.4.2.

4.1.3 Calibration / Check at Innovision

In accordance with the Instructions for Use it is recommended that the manufacturer perform a number of calibrations periodically on a 12 months basis. Calibrations by Innovision comprise the same calibrations as those performed by the distributor plus the following:

a) Pulse oximeter: Performance check using a special calibration kit.

b) NIBP pressure transducer: Gain calibration using a reference transducer and a vessel (reservoir). The test includes also a leak test and a check of the safety timer.

c) Photo acoustic analyser: Check on the gas mixture (see above), and an exercise test from 0 to 125 watt [0, 25, 50, 75, 100 & 125 watt] simultaneously with a reference instrument. If major deviations are found a multi-point calibration is performed.

d) Gas pressure sensor: The gain calibration is checked.

4.1.4 Enter service mode of Innocor

In order to make the different calibrations / checks of the Innocor the Service part of the Innocor s/w must be entered.

Select **Setup** from the main menu and press **Service**. To access the service functions of Innocor the corners in the message box below must be pressed in a specific order – see figure 4.1.4-1 below:

Figure 4.1.4-1 “Key” to entering service module.

4.2 CALIBRATION OF GAS FILLING FLOW

4.2.1 Adjustment of low pressure

Before calibrating the bolus flow it is recommended to check the pressure output of the secondary flow regulator. It is normally not necessary to adjust the pressure – it is preset during factory calibration to approx. 0.45 bar. But if some problems occur during bolus calibration or one of the ports of the RVU are not able to close properly, it is recommended to check or adjust the pressure.

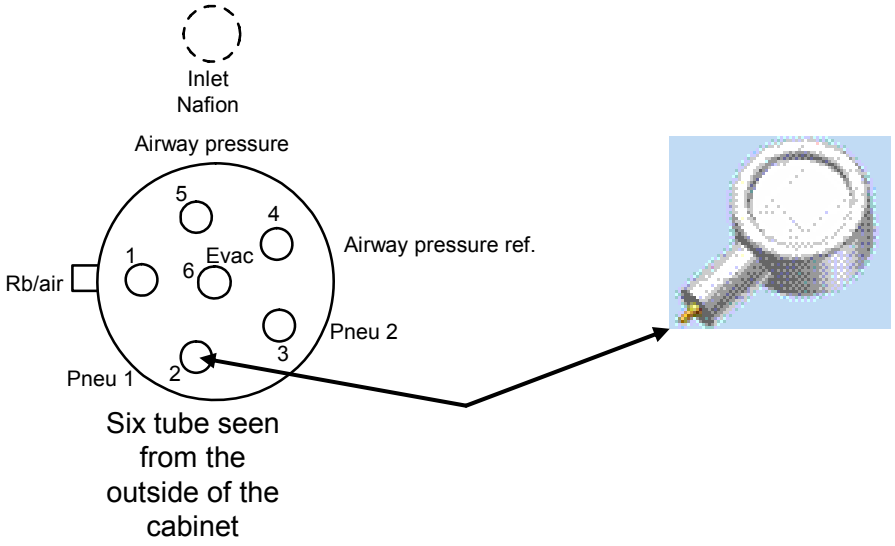


Figure 4.2.1-1 Six tube connector.

Gas Bottle [Bar]	Pressure on Pneu 1 [Bar]
115	0.430
110	0.431
106	0.434
101	0.435
97	0.437
92	0.440
88	0.442
83	0.444
79	0.446
74	0.446
69	0.448
64	0.451
60	0.453
55	0.456
50	0.458
45	0.461
40	0.463
36	0.466
31	0.469
26	0.472
20	0.477

Table 4.2.1-1 Set point for Pneu 1 pressure at different gas bottle pressure.

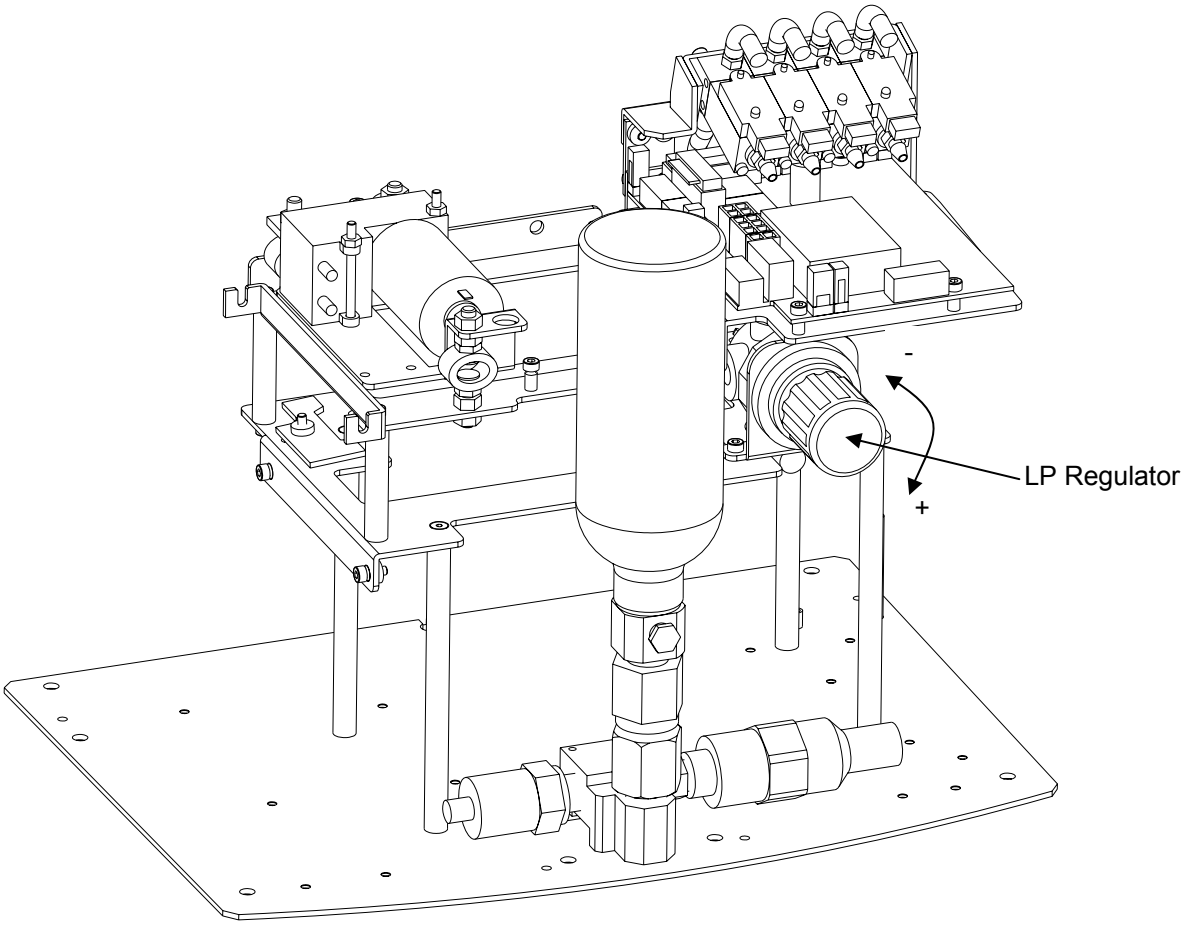


Figure 4.2.1-2 LP regulator.

Adjustment of "LP regulator":

- Connect a pressure sensor to the Pneu 1 line on the six tube connector, see figure 4.2.1-1
- Pull out the knob of the LP regulator, see 4.2.1-2.
- Turn clockwise to increase (+) and counter-clockwise (-) to decrease pressure. To reduce pressure, first reduce to a pressure less than that desired, and then increase to the desired pressure.
- Pull in the knob to fix the setting.

Use the service program in Innocor to manual control pressure on Pneu 1.

- Enter the service program of Innocor
- Select **Misc**.
- Select **Press Sensor**
- Read the gas bottle pressure
- Select **Valve**
- Press **Pneu 1** to activate/deactivate pressure on Pneu 1 line.
- Adjust the LP regulator according to table 4.2.1-1.
- If the flow regulator is changed, the bolus filling must be recalibrated, see section 4.2.3.

As mention above when decreasing pressure, first reduce to a pressure less than that desired, next deactivate/activate Pneu 1 line before increasing to the desired pressure.

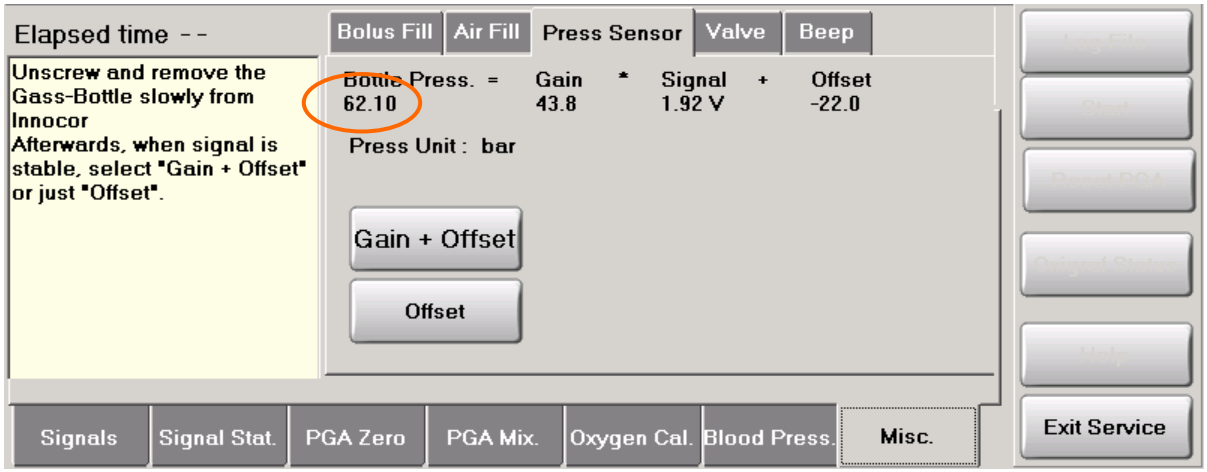


Figure 4.2.1-3 Menu for reading the bottle pressure.

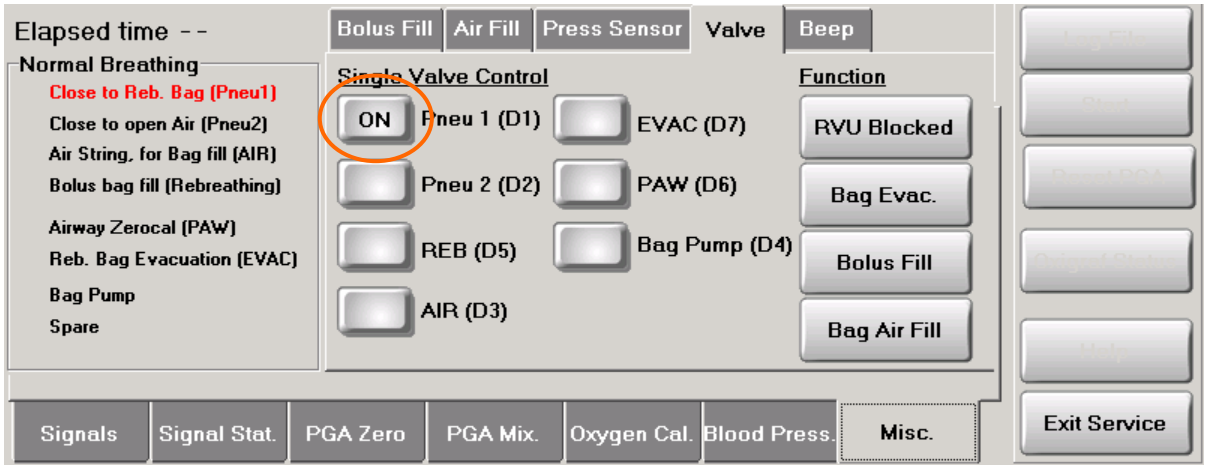


Figure 4.2.1-4 Menu for manual control of the Pneu 1 gas line

4.2.2 Preparation of bolus and air filling calibration

When calibrating the filling flow (bolus gas and air) on Innocor, the following components are needed:

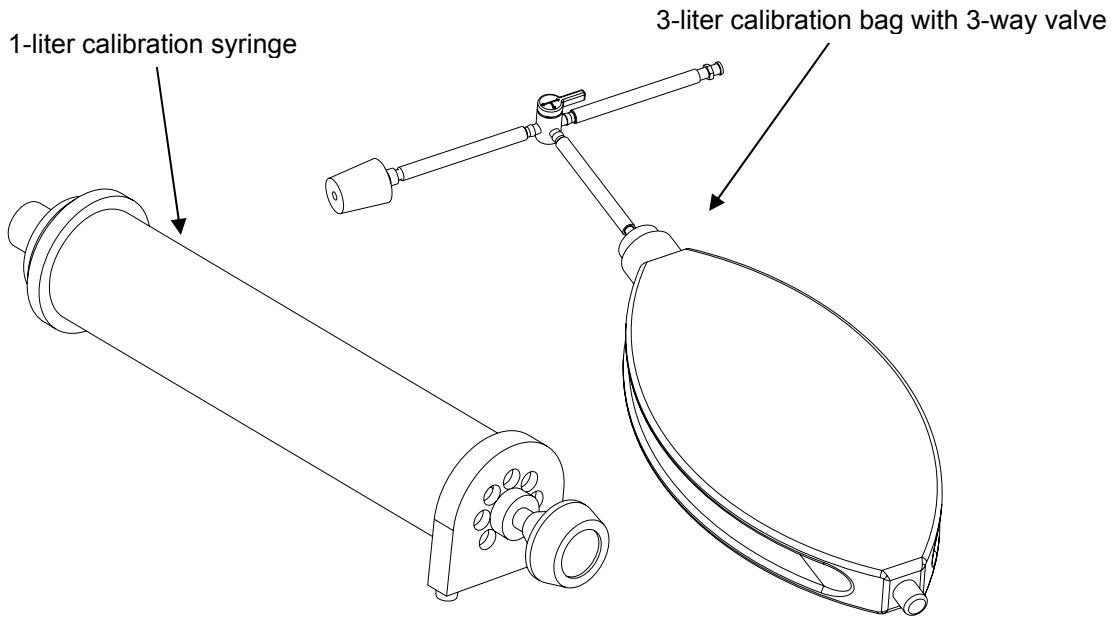


Figure 4.2-1 Components for gas filling calibration.

The setup for a filling flow calibration:

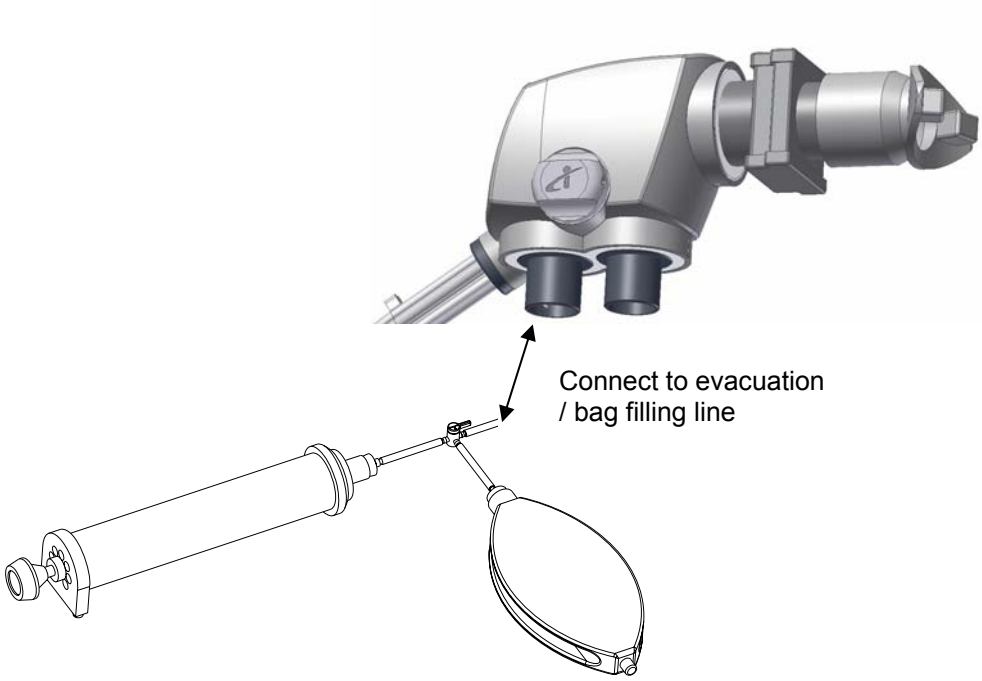


Figure 4.2-2 Setup for gas filling calibration.

Connect the Respiratory Valve to the 3-liter calibration bag (see detailed view above).

4.2.3 Bolus calibration

The calibration of the bolus is a calibration of the bolus filling flow, which typical is in the range of 20-70 ml/s. (Most of the Innocor models below xxxx098 is in the range 50-70 ml/s, where models with and after xxxx098 is in the range 20-45 ml/s). An incorrect bolus filling flow will result in the messages too low or too high insoluble gas concentration after a rebreathing test. The accuracy of the bolus filling flow is not very critical, since the main bag volume is coming from the air fill, and because the concentration of the mixed gases is measured during the first inspiration. However the warning messages too low or too high insoluble gas concentration can also be a result of an incorrect air filling, in which cases the calculated rebreathing results will be erroneous. Therefore it is recommended to check the bolus flow routinely, e.g. once a year.
Note: the first filling of a bag after a longer period with pressure in the gas supply can give the warning “too high insoluble gas concentration” after a rebreathing test. This is normal and is caused by a small diffusion of gas through the wall of the tubings. The SF_6 gas is heavier with a slower diffusion than the other components, and over time the concentration of the insoluble SF_6 gas will increase.

- Turn the 3-way valve so that the calibration bag and the respiratory valve are connected:

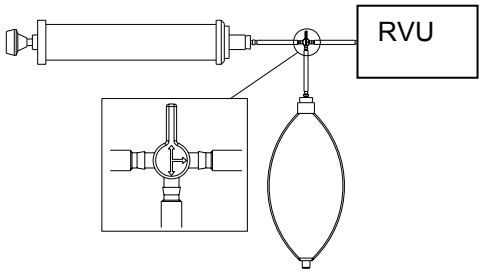


Figure 4.2.1-1 Setup for bolus calibration – 1st step.

When the calibration setup is ready, enter Service menu of Innocor.

- From the "**Misc**." menu choose "**Bolus Fill**".
- Press the "**Set Bolus Vol**." button.
- Enter the desired bolus volume and press "OK", e.g. 300 ml and press OK.
- Note down the original flow speed.
- Press "**Test Bolus**".

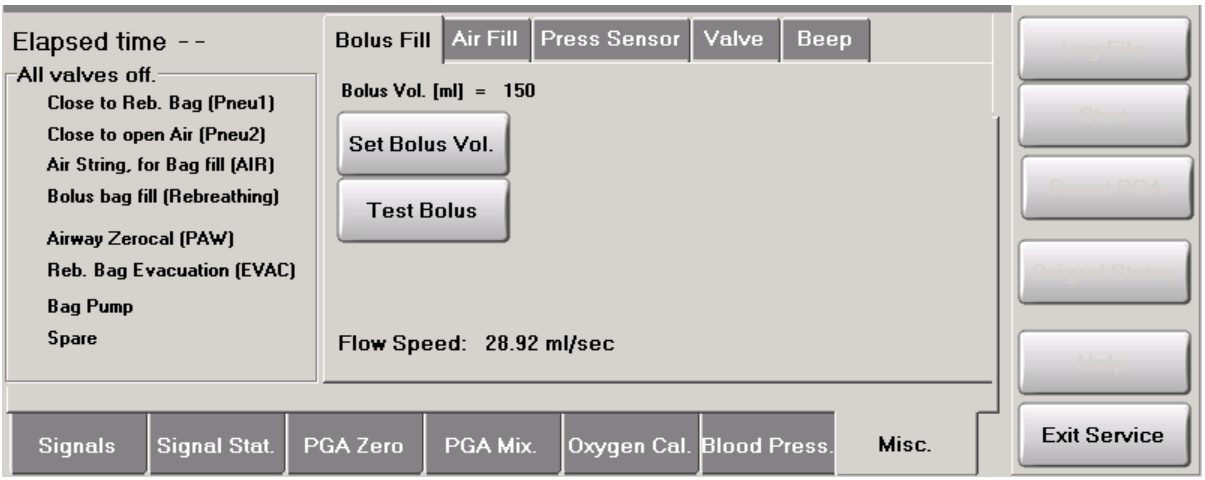


Figure 4.2.1-2 Menu for bolus calibration.

The 3-liter calibration bag will now be emptied and immediately hereafter the bolus filling will start.

- When the bolus filling is finished, turn the 3-way valve so that the syringe and the calibration bag are connected (make sure that the syringe is completely empty before turning the valve):

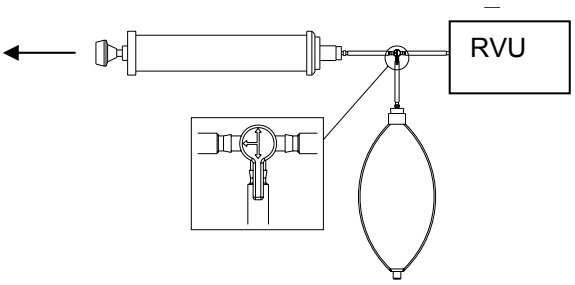


Figure 4.2.1-3 Setup for bolus calibration – 2nd step.

- Measure the bolus volume in the bag by pulling the syringe piston. When the calibration bag is completely emptied, read the measured volume and type in the value. Note, that the measured volume is one litre minus the reading on the scale! When the bag is nearly empty, it is important not to overstress the syringe piston. The calibration bag can be considered empty, when it visually looks like the bag, when Innocor has emptied it.

The bolus flow is now calibrated.

- Perform the bolus calibration procedure again to check that the flow is correct. Ideally, the desired bolus volume in this second filling should be somewhat different from the first (e.g. decreased by 50%). Irregularities in the bolus flow are hereby more likely to be revealed.

If the desired bolus volume matches the measured bolus volume within ±5% relative and the bolus flow is within the range 20-70 ml/s, the calibration is OK (Most of the Innocor models below xxxx098 has a bolus flow in the range 50-70 ml/s, where models with and after xxxx098 is in the range 20-45 ml/s). However compare the new bolus flow with the original bolus flow, and e.g. check the pressure of the secondary flow regulator (see section 4.2.1) if the difference is more than 10%.

If the bolus fill is lower than 20 ml/s, the cause can be that the filling line is occluded, or the output pressure of the second pressure regulator is too low.
If the bolus fill is greater than 70 ml/s, the output pressure of the second pressure regulator is probably too high.

4.2.4 Air filling calibration

The calibration of the air filling is a calibration of the air filling flow, which typical is in the range of 50-60 ml/s. An incorrect air filling flow will result in the messages too low or too high insoluble gas concentration after a rebreathing test. The accuracy of the air filling flow is more critical than the bolus filling, since the main bag volume is coming from the air fill. A 5% error on the air filling flow will result in a 4.5% error on the bag volume, which again will result in a 4.5% error on most of the calculated results. It is - like for the bolus flow - recommended to routinely check the airflow, e.g. once a year.

- Turn the 3-way valve so that the calibration bag and the respiratory valve are connected:

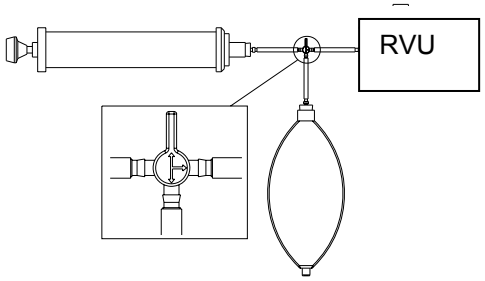


Figure 4.2.4-1 Setup for filling calibration – 1st step.

- From the "**Misc**." menu choose "**Air Fill**".
- Press the "**Set Air Vol.**" button.
- Enter the desired air volume and press "OK", e.g. 2500 ml and press OK.
- Note down the original flow speed.
- Press "**Test Air Vol.**".

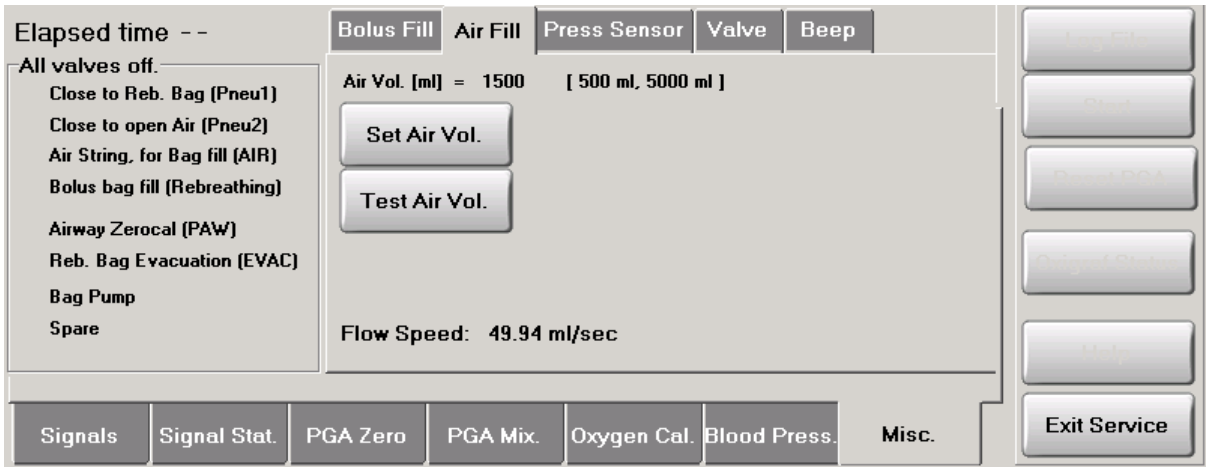


Figure 4.2.4-2 Menu for air filling calibration.

The 3-liter calibration bag will now be emptied and immediately hereafter the air filling will start.

- When the air filling is finished, turn the 3-way valve so that the syringe and the calibration bag are connected (make sure that the syringe is completely emptied before turning the valve):

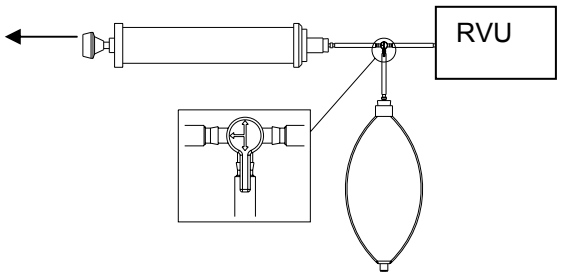


Figure 4.2.4-2 Setup for filling calibration – 2nd step.

- Measure the air volume in the bag by pulling the syringe piston. The desired air volume is often larger than the capacity of the syringe. Therefore it can be necessary to empty the syringe once or twice during the measurement of the air volume. Empty the syringe by first turning the 3-way valve to close the connection to the calibration bag. Then pull the tapered silicone plug and empty the syringe by pressing down the piston – see figure 4.2.4-3.

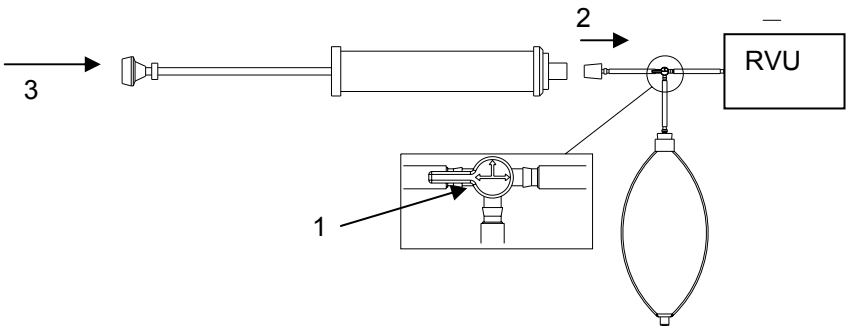


Figure 4.2.4-3 Setup for filling calibration – 3rd step.

- Repeat the procedure until the calibration bag is completely empty. The calibration bag can be considered empty, when it visually looks like the calibration bag when Innocor started the bolus filling. Note, that the measured volume is one litre minus the reading on the scale!

The Air Flow is now calibrated.

- Perform the air calibration procedure again to check that the flow is correct. Ideally, the desired air volume in this second filling should be somewhat different from the first (e.g. decreased by 50%). Irregularities in the airflow are hereby more likely to be revealed.

If the desired air volume matches the measured air volume within ±3.5% relative and the airflow is above 50 ml/s, the calibration is OK.

If the air fill is lower than 50 ml/s the cause can be that the filling line is occluded.

4.3 GAS CALIBRATION / CHECK

4.3.1 General consideration

When exposing a gas to the inlet of the Innocor, the inlet must be disconnected at the RVU end and connected to the T-connector on the calibration unit. When the gas is opened the flow out of the calibration unit must be higher (200-300 ml/min) than the flow of the inlet (120 ml/min).

4.3.2 O_2 calibration

The O_2 signal is measured by the Oxigraf sensor and sent to the PGA via an analogue line. The calibration of the O_2 signal can be performed in both the Oxigraf and the PGA. A complete calibration of the O_2 signal is performed by first calibrating the Oxigraf, then the PGA. A simpler 1-step calibration is also possible by adjusting the baseline of the Oxigraf.

1-step calibration (user calibration)

- Let the Innocor warm up for at least 10 minutes
- Expose inlet to ambient air (20.93% O_2)
- Enter the **Setup** of Innocor
- Press **Calibration**
- Press **O2 Adjust**
- Press **Start** when current signal is stable
- Wait for the calibration to complete
- Press **Save**

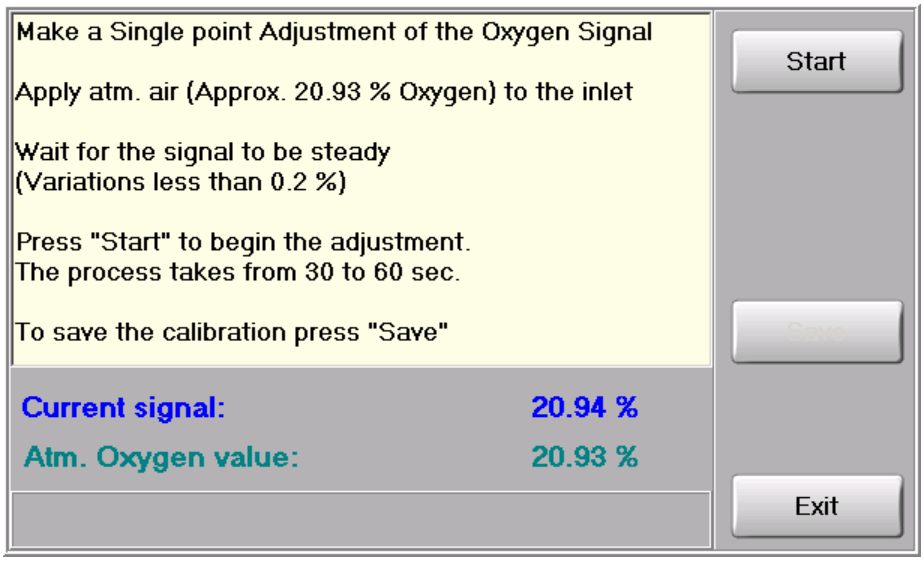


Figure 4.3.2-1 Menu for 1 step oxygen calibration

Complete 2-step calibration (distributor calibration)

- Let the Innocor warm up for at least 10 minutes
- Enter **Setup** of Innocor
- Press **Service** to enter the service program
- Press the tab **Oxygen Cal.**
- Press **Set High Conc.**
- Set concentration to 100% (or 50%)
- Expose inlet to high O_2 concentration (100% or 50%)
- Press **Accept Signal** when signal is stable (Dig. Oxygen)
- Expose inlet to ambient air (20.93% O_2)
- Press **Set Low Conc.**
- Set concentration to 20.93%
- Expose inlet to ambient air (20.93% O_2)
- Press **Accept Signal** when signal is stable (Dig. Oxygen)
- Press **Save and Exit**
- Oxigraf is now calibrated
- Expose inlet to ambient air (20.93% O_2)
- Press **Accept Signal** when signal is stable (Dig. Oxygen)
- Expose inlet to high O_2 concentration(100% or 50%)
- Press **Accept Signal** when signal is stable (Dig. Oxygen)
- Press **Save**
- PGA is now calibrated with respect to the O_2 signal
  Zero signal, zO2 should be in the range -1 to 1
  Slope, kO2 should be in the range 0.19 to 0.21

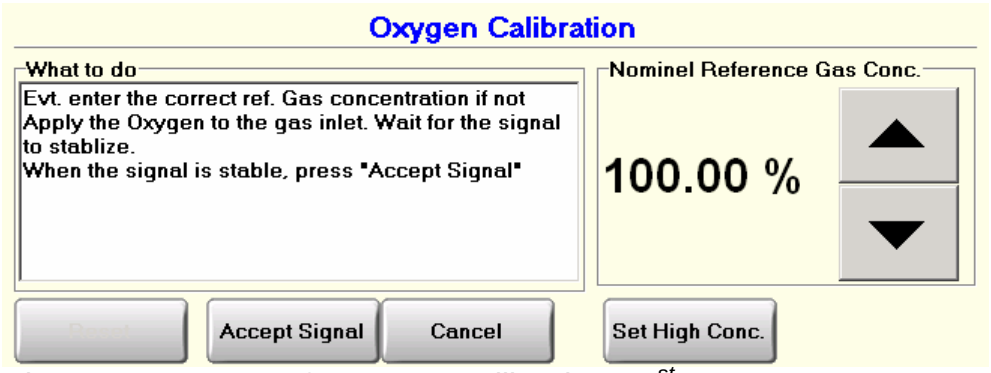


Figure 4.3.2-2 Menu for oxygen calibration – 1st step

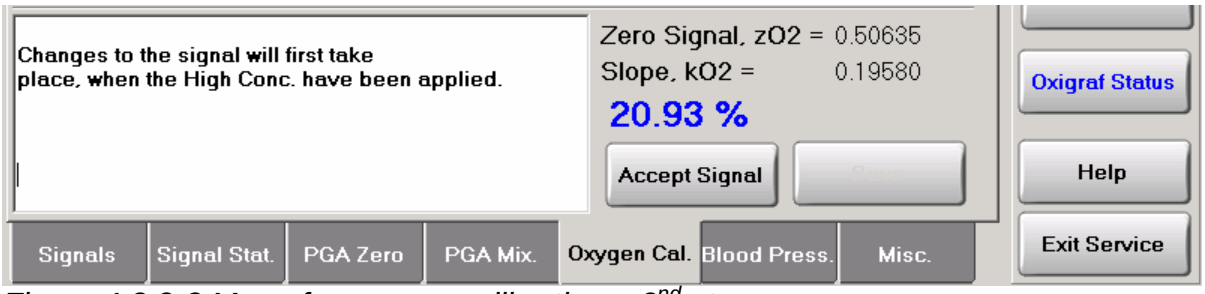


Figure 4.3.2-3 Menu for oxygen calibration – 2nd step

4.3.3 CO_2, SF_6 & N_2O calibration

The calibration of the PGA signals: CO_2, SF_6 & N_2O can be performed by a 2-step calibration or a multi-step calibration. The 2-step calibration adjusts the zero point and the gain of the signals. The multi-step calibration adjusts gain, offset, linearity and cross talk. It is recommended to have the CO_2, SF_6 & N_2O checked routinely, e.g. 1 time a year.

Gain & offset calibration (distributor calibration)

- Enter **Setup** of Innocor
- Press **Service** to enter the service program
- Press the Tab **PGA Zero**
- Let the Innocor warm up for at least ½ hour. The temperature of the gas analyser shown in the menu should approx. be 15° K higher than room temperature. (273° K = 0° C).
- The **Press.** signal should be 17-19 hPa below ambient, i.e. approximately 83 hPa @ 101.3 hPa.
- Expose inlet to zero gas (20% O_2 and 80% N_2)
- Press **Oxygen Conc.** and enter 20%
- Wait until amplitude signals are stable (should be below 0.1 for SF_6 & CO_2, and below 0.35 for N_2O)
- Press **Make Calc.**
- Press **Save**
- PGA is now calibrated with respect to offset on the CO_2, SF_6 & N_2O signals
- Press the tab **PGA Mix**.
- Expose inlet to mixture gas (50% O_2, 1% N_2O, 0.2% SF_6, 5% CO_2, bal. N_2)
- Check or enter the gas concentrations of the mixture gas
- Wait until amplitude signals are stable
- Press **Make Calc.**
- Press **OK**
- Press **Save**
- PGA is now calibrated with respect to gain on the CO_2, SF_6 & N_2O signals

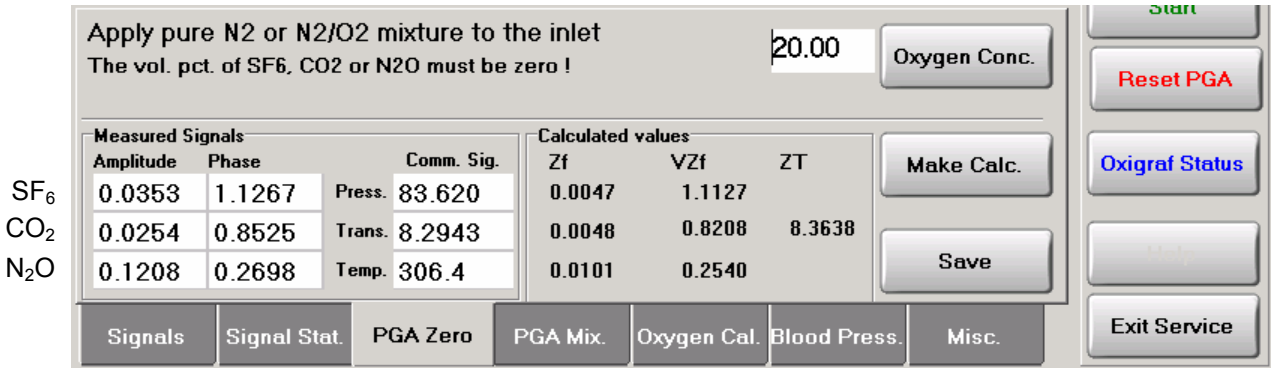


Figure 4.3.3-1 Menu for PGA zero calibration

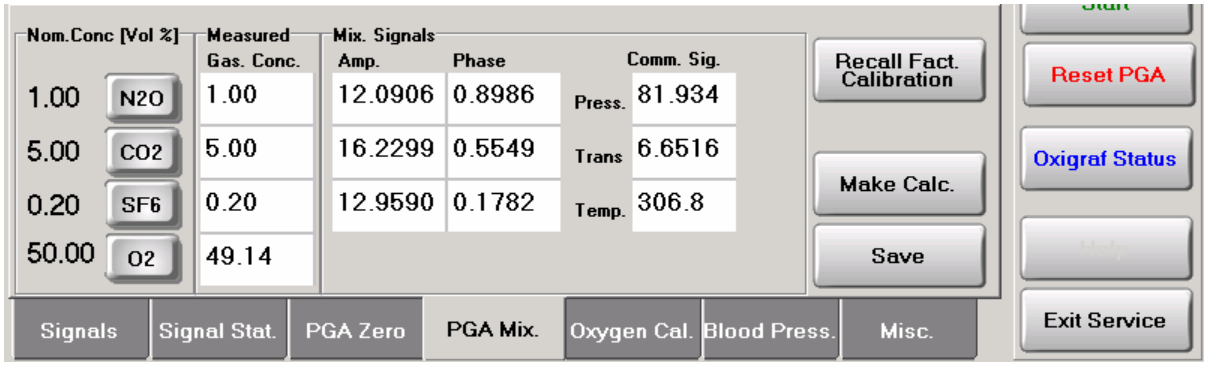


Figure 4.3.3-2 Menu for PGA Mix calibration

Multi-step calibration (factory calibration)

A multi-step calibration of the PGA signals can only be performed at Innovision or by qualified trained personnel. The calibration is performed as a factory calibration and requires the following gases:

- A zero gas (20% O_2 and 80% N_2)
- 3 phase gases (5% N_2O, 1% SF_6 & 10% CO_2 – all in 20% O_2, balance N_2)
- 3x3 lin/span gases:
  0.1, 0.5 & 5.0% N_2O
  0.02, 0.1 & 1.0% SF_6
  1.0, 5.0 & 10.0% CO_2
  (all in 20% O_2 and balance N_2)

4.3.4 SNR test

A signal to noise test on the gas signals is a way to determine the quality of the gas signals.

- Enter the service program of Innocor
- Select the gases to measure in **Signals** by turning them into *italics.* (Use **Select Stat.** with mode *"Press signal name to select"*). See figure 4.3.4-1.
- Select **Signal Stat**.
- Enter 1000 samples corresponding to 10 seconds
- Expose a test gas containing gas concentration of the signals to measure
- Wait until the gas signals are stable by looking at the graphic display, see figure 4.3.4-2.
- Press **Start**
- Typical SNR's:
  - O_2 @ 50%: SNR > 1000
  - O_2 @ 20.95%: SNR > 500
  - CO_2 @ 5%: SNR > 400
  - SF_6 @ 0.2%: SNR > 1000
  - N_2O @ 1%: SNR > 1000
- If one or more of the SNR's are significantly low, the PGA must be returned for service.
- The following inspections can however be performed before returning the PGA:
  - Is the inlet particle filter clean?
  - Is the PGA platform free floating – no tube or wire pressing on the platform?

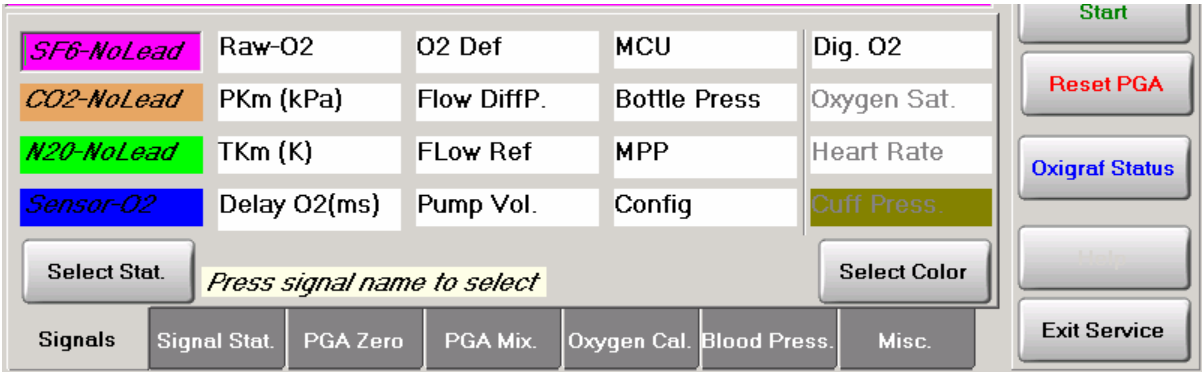


Figure 4.3.4-1 Menu for selecting channels for SNR measurement

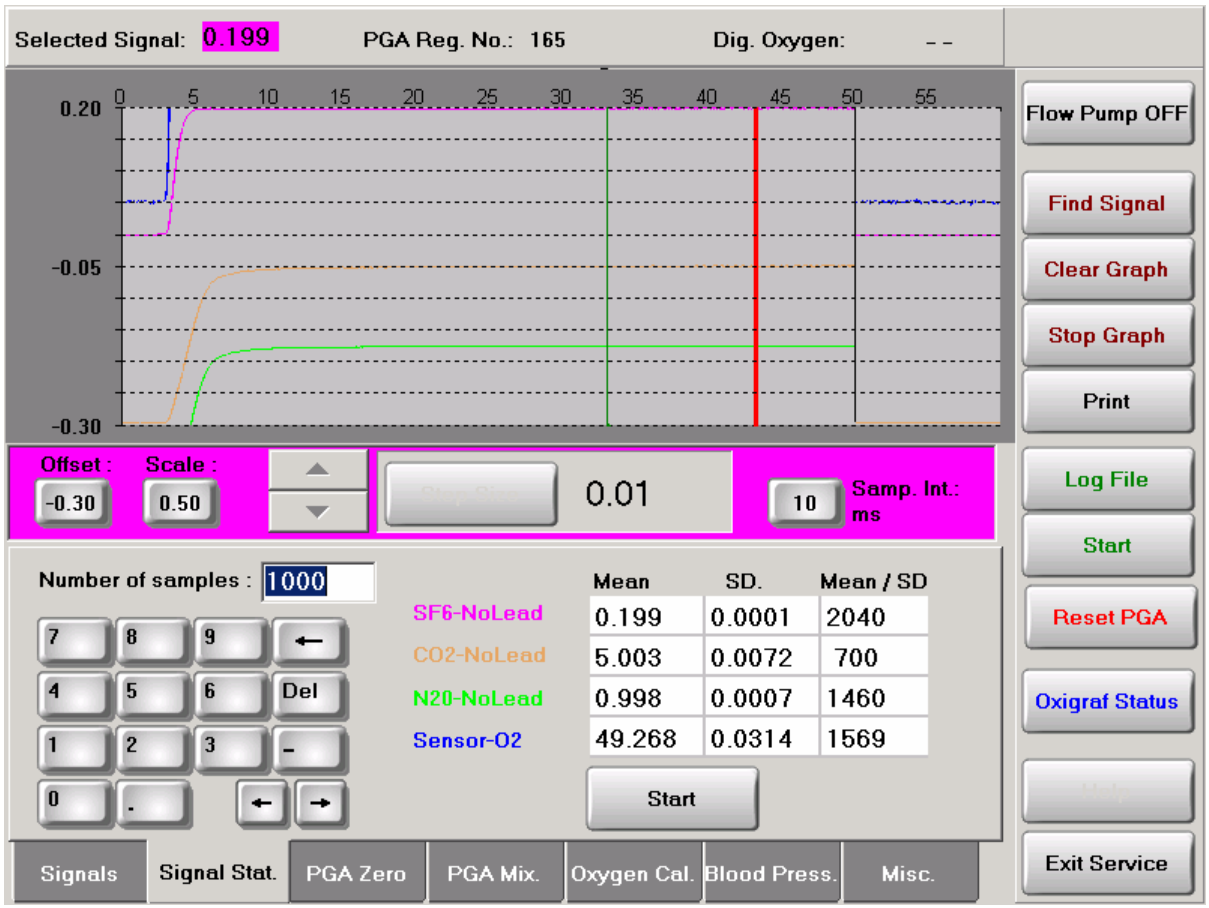


Figure 4.3.4-2 Menu for SNR measurement

4.4 FLOWMETER CALIBRATION

The flowmeter is calibrated by:
- an offset
- a gain factor
- a linearization table

The offset is as default done automatically every 60 seconds, and can be adjusted by the following lines in hardware.ini:

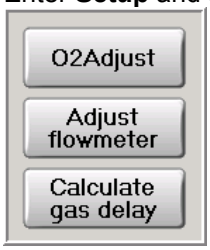
```
[BBB]
Installed=1
FlowzeroAfterRB = 1
FlowZeroInterval = 60
```

The calibration of the gain factor is a user calibration and recommended every day and if the flowmeter screen is changed.

The calibration of the linearization table is a factory / service calibration and is recommended once a year, or if the gain factor calibration differs from low & high flow.

4.4.1 Flowmeter gain calibration

Enter **Setup** and select **Calibration** – **Adjust Flowmeter.**



Connect a 1 litre or 3 litre calibration syringe to the RVU, and set the s/w switch accordingly (**Syringe 1 litre** or **Syringe 3 litre**).

Figure 4.4.1-1 Menu for flowmeter gain calibration

- Empty the syringe
- Press **Calibrate** to start the calibration.
- Fill the syringe at a relatively low rate without “bumping” at the end.
- When the s/w is ready empty the syringe – again at a low rate.
- Repeat the filling and emptying until 2x5 strokes have been applied, and the **OK** button is highlighted.

- Increase the flow rate at each of the 2x5 strokes in order to try to cover the physiological test range.
- Press **OK** if the new gain values are in the range 0.9 to 1.1, otherwise replace the flowmeter screen and repeat the calibration.

Note: The flowmeter is automatically offset adjusted prior to each 2x5 strokes.

The measured volumes should be within ±2% relative after a gain calibration, i.e. ±0.02 litre @ 1 litre calibration syringe and ±0.06 litre @ 3 litre calibration syringe. If this is not the case a calibration of the flowmeter linearization table is needed.

4.4.2 Calibration of flowmeter linearization table

The conductance characteristic of the flowmeter (a pneumotachometer) is not absolutely linear. This means, that when highly accurate flow measurements are required, a linear calibration is insufficient, since it assumes a constant conductance over the entire flow range.

In the flowmeter linearization, a look up table is generated, which contains voltage-to-flow conversion factors (also referred to as gain factors below) for a number of equidistantly spaced voltages. By table look up, each measured voltage is converted to a flow value by multiplying the corresponding gain factor from the table.

The Innocor has a built-in standard factory flowmeter calibration table based on a weighted-averaging technique (Yeh et al. 1982), whereby a series of multiple strokes from a precision calibrated syringe are made.

A generation of the linearization table is a factory calibration and should only be performed at Innovision or by qualified trained personnel. The calibration procedure is:

- Let the Innocor warm up for at least ½ hour.
- Leave Innocor software and go to Windows. (On the Innocor main screen press right-top corner followed by left-top corner).
- Select **Flowmeter Calibration** from C:\Innocor\ShortCut or C:\Innocor\Program.
- Press **Calibrate.**
- Connect a gas bottle in order to close the rebreathing port during calibration.
- Connect a 3-litre syringe to the flowmeter.
- Press **Prepare**, see figure 4.4.2-1.
- Select **New Table.**
- Press **Add Stroke**, see figure 4.4.2-1.
- Note the offset voltage, see figure 4.4.2-2. It should be in the range ±200 mV. (If not adjust it, see section 3.4).
- Fill and empty the syringe 5 times, see notes below for a recommended procedure.
- If all strokes are performed OK, press **Accept.**
- If the Gain curve is noisy, press the **Filter** button one or more times, see figure 4.4.2-3.
- Repeat **Add Stroke** until the accuracy on all volumes are below 1%, see figure 4.4.2-4.
- Press **Prepare.**
- Select **Save table.**
- **Save** file as C:\Innocor\Setup\bbblin1.cal, see figure 4.4.2-6.
- Press **yes** to overwrite file.
- Press **Cancel.**
- Press **yes** to save changes.
- Press **Exit.**

A recommended procedure for generating the flow table is:
- Start with a single fill & empty of the syringe at 1-2 l/s and save it in order to find a start point for the inspiration & expiration gain.
- Perform 2x5 stokes below 1 l/s

- Perform 2x5 stokes in the range 1 to 3 l/s
- Perform 2x5 stokes in the range 3 to 5 l/s
- Perform 2x5 stokes above 5 l/s
- Perform 2x5 stokes in the range 3 to 5 l/s
- Perform 2x5 stokes over the complete range, and repeat it until the volume accuracy is below 1%

Note:

- Fill and empty the syringe without “bumping” at the end.
- Use the **Filter** function to remove noise on the Gain curve
- The first time calibration of the high flow disturbs the flow calibration at medium flow, and it is therefore necessary to repeat the medium flow calibration after the high flow calibration.
- It is possible to use a 1-litre syringe for the flowmeter calibration, but it is **not** recommended. It is very difficult to generate the high flow rates with a 1-litre syringe.

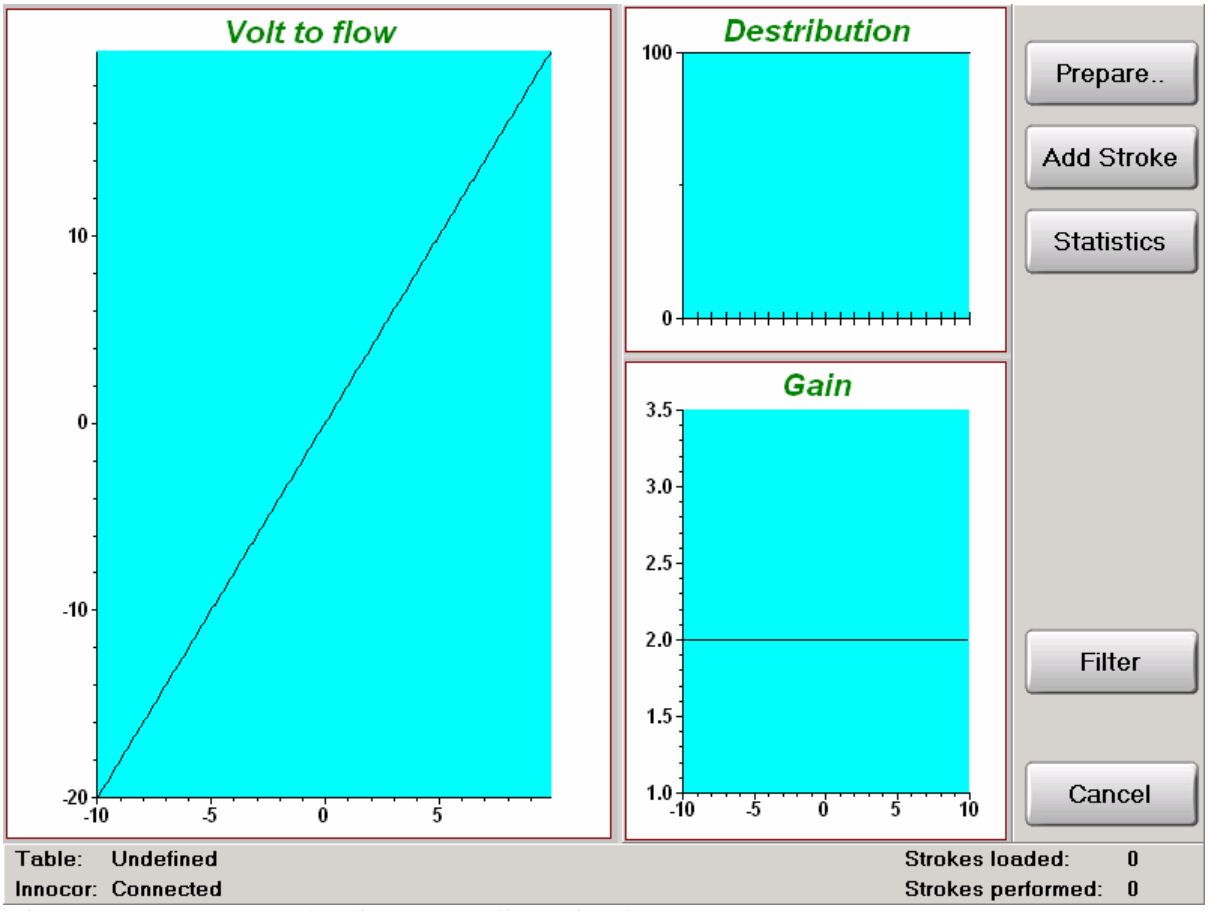


Figure 4.4.2-1 Menu for flowmeter linearization

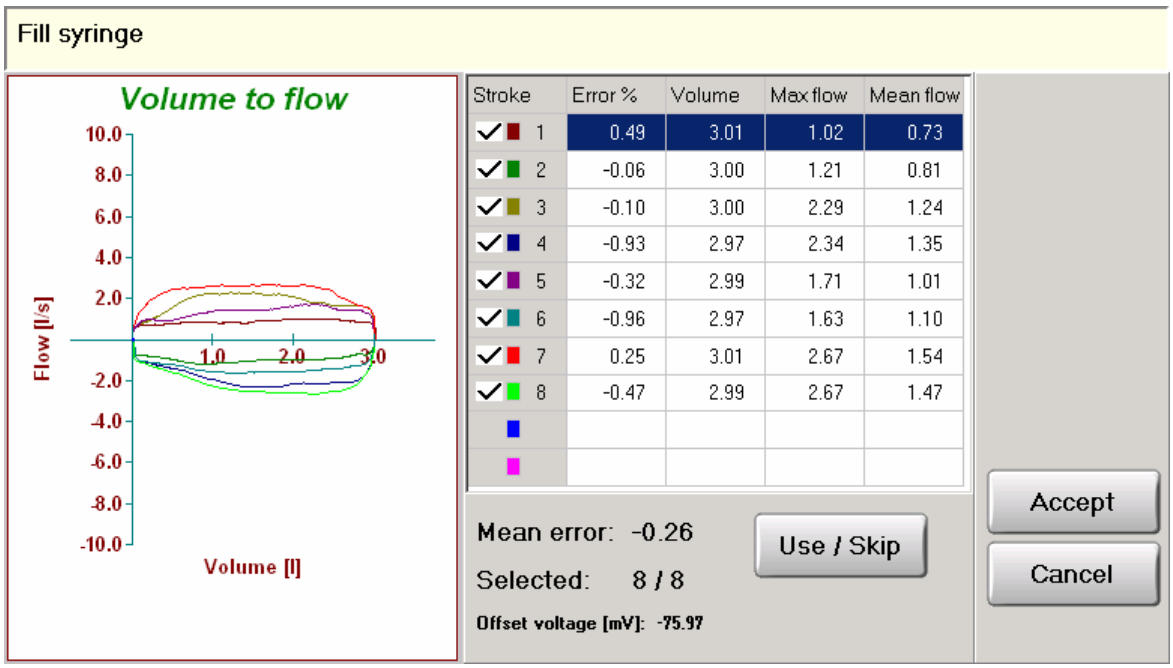


Figure 4.4.2-2 Menu for entering 2x5 strokes

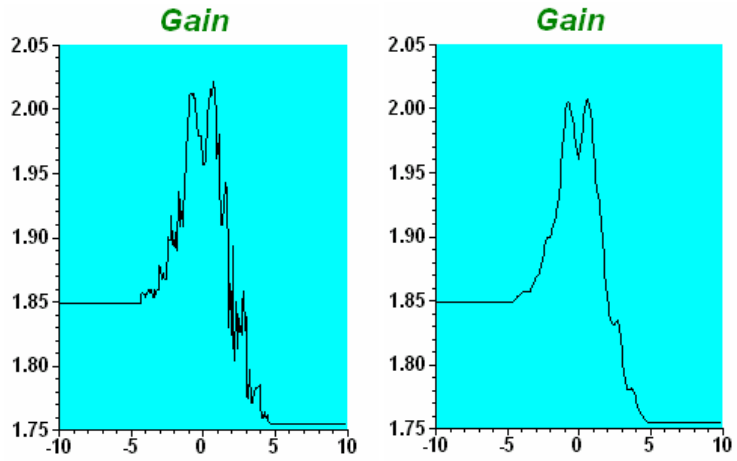


Figure 4.4.2-3 Gain curve before and after filtering (6xFilter)

Use the filter function until the noise on the gain curve disappears.

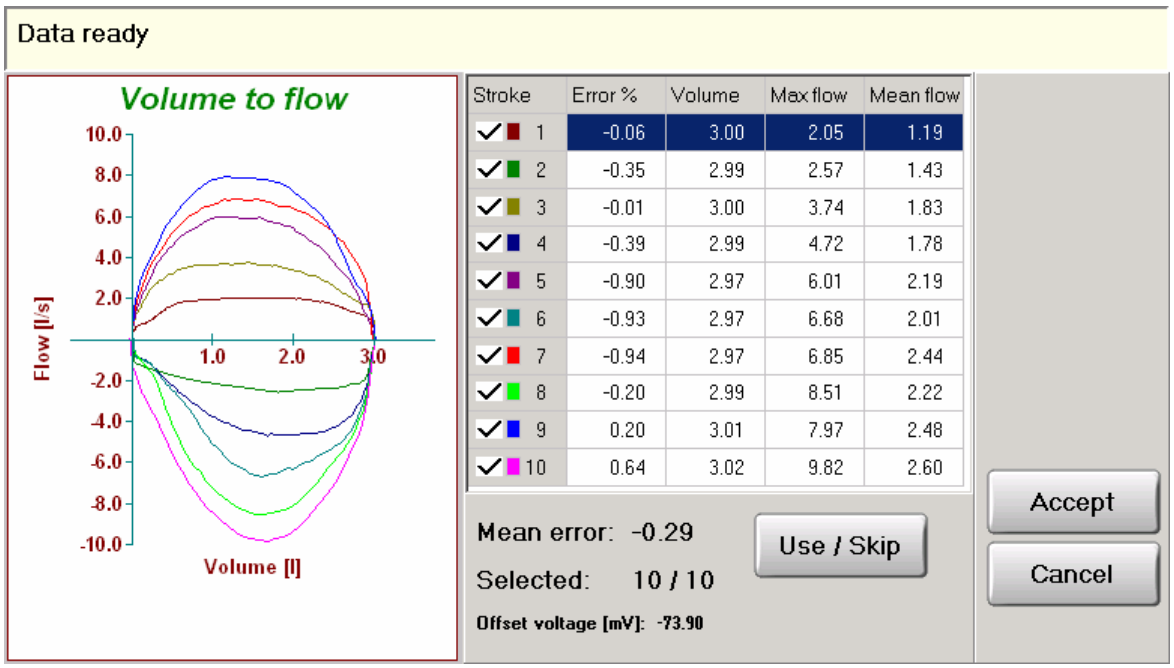


Figure 4.4.2-4 Final check at different flows

The final check of the calibration should show errors below 1% at different flow rates. Try to cover the complete physiological range of the subjects.

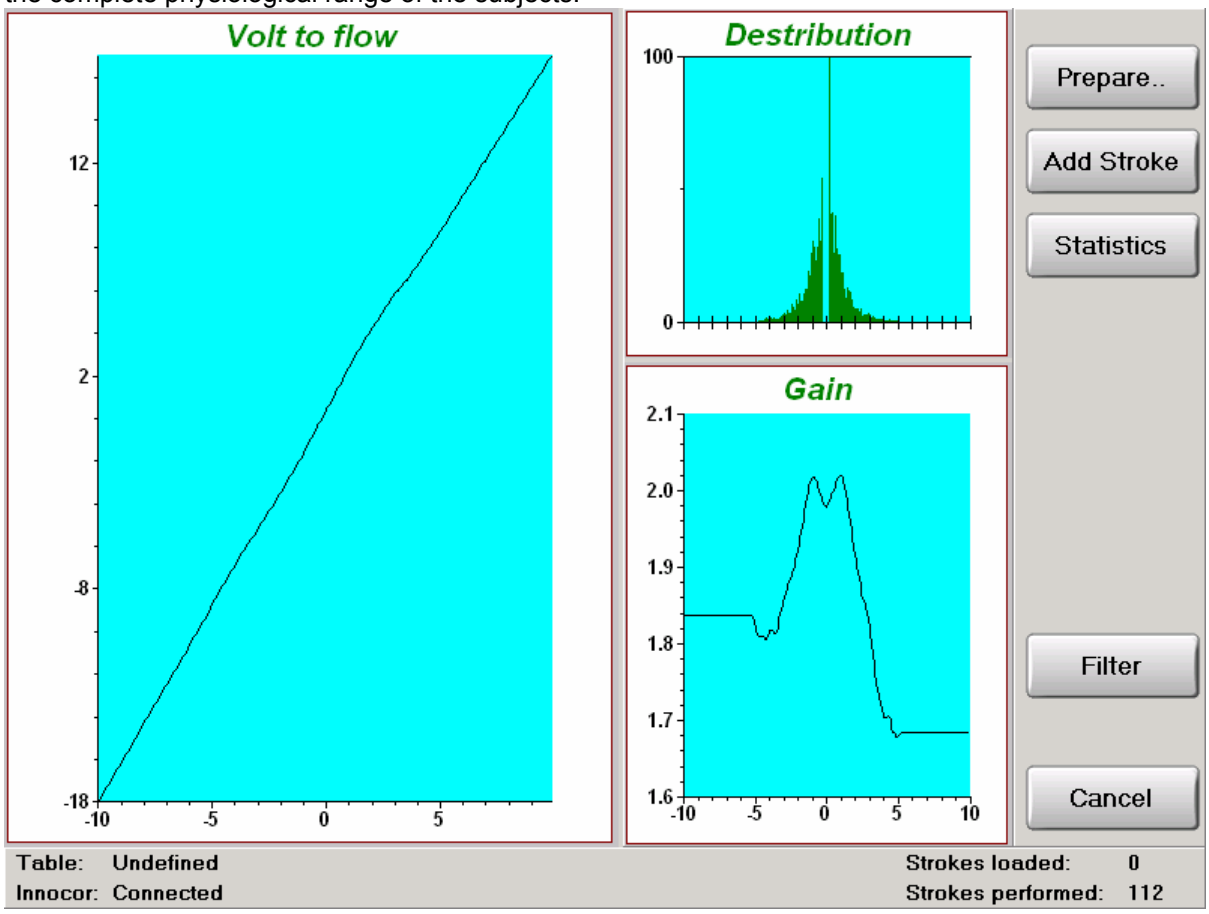


Figure 4.4.2-5 Final flowmeter linearization

The distribution curves shows at which flow rates the flowmeter is calibrated. Every used sampled is displayed in the normalised distribution plot.

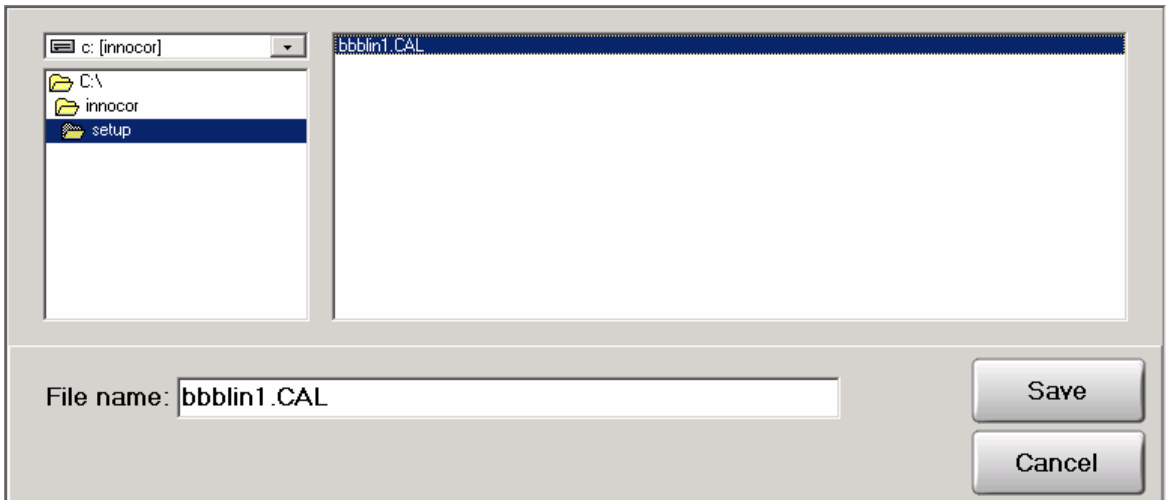


Figure 4.4.2-6 Menu for saving flowmeter linearization

The flowmeter table must be saved in C:\Innocor\Setup\bbblin1.cal in order to be used by the Innocor software afterwards.

4.5 FLOW-GAS DELAY CALIBRATION

4.5.1 Method

The Breath-by-Breath calculation contains an integration of the product of flow and gas, and because the gas measurement is delayed through the sample line, it is necessary to correct for this delay. The delay is typical in the range 1400 to 1600 ms, but can vary from instrument to instrument. A change of the inlet sample line can also change the delay. A longer delay is normally caused by a reduced inlet sample flow, probably caused by a dirty particle filter on the inlet sample line.

The flow gas delay is calibrated by looking at the gas and flow change during the shift from expiration to inspiration. The calculation is taking into account the dead space volume from the inlet out to ambient air, which is 45 ml for a standard configuration. In order to have an accurate flow gas delay calibration the inspiration must be fast / forced, and an average of up to 10 breaths is used to improve the determination.

The calibration of the flow-gas delay is critical – an error of 25 ms can give a 5% error on the Vo_2 and Vco_2 results!

It is recommended to perform the flow gas delay calibration every day.

When performing a Breath-by-Breath exercise the flow gas delay is as default automatically adjusted when the exercise level exceeds a certain level – typical above 1/3 of the subjects maximum exercise level.

4.5.2 Setup

The automatically adjusted flow gas delay can be turned off in the BBBctrl.ini using the following lines:

```
[flowGasDelay]
OnlineCalc=1
Co2Calc=0
```

When the `OnlineCalc=1` (default) the flow gas delay is automatically adjusted. When 0 the automatically adjustment is turned off. `Co2Calc=0` (default) means that the automatic adjustment only calculates the O_2 delay and then corrects the CO_2 delay with the same amount. If `Co2Calc=1` the automatic adjustment calculates both the O_2 & CO_2 delay, which is not recommended, because the O_2 delay calculation is more accurate during exercise breathing.

If the flow gas delay calibration is not performed with the standard RVU the volume of the dead space between the inlet and ambient air must be changed in the BBBctrl.ini file:

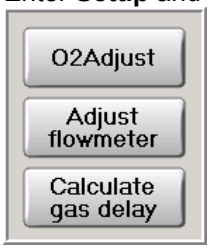
```
[Deadspace]
Valve=0.045
```

Similar the flowmeter dead space (the volume from the mouth to the inlet) must be changed in the BBBctrl.ini file:

```
[Deadspace]
Flowmeter=0.12
```

4.5.3 Calibration procedure

Enter **Setup** and select **Calibration** – **Calculate gas delay.**



Wait 1 minute for warm up.
When warmed up the operator (not the subject) starts breathing in and out of the RVU. When ready the **Calibration** button is pressed. The operator must then make 11 slow expirations followed by 11 very fast inspirations until the **OK** button is highlighted. The inspirations have to be fast in order to get a precise determination of the flow-gas delay. If one or two breaths fail the software will automatically filter these results. The delays should not vary more than 20-40 ms from day to day, if the same gas sample inlet is used.

Note:

- A gas cylinder must be connected in order to close the RB valve during the delay calibration.
- The BBB port on the RVU must not be connected to other devices during the delay calibration.

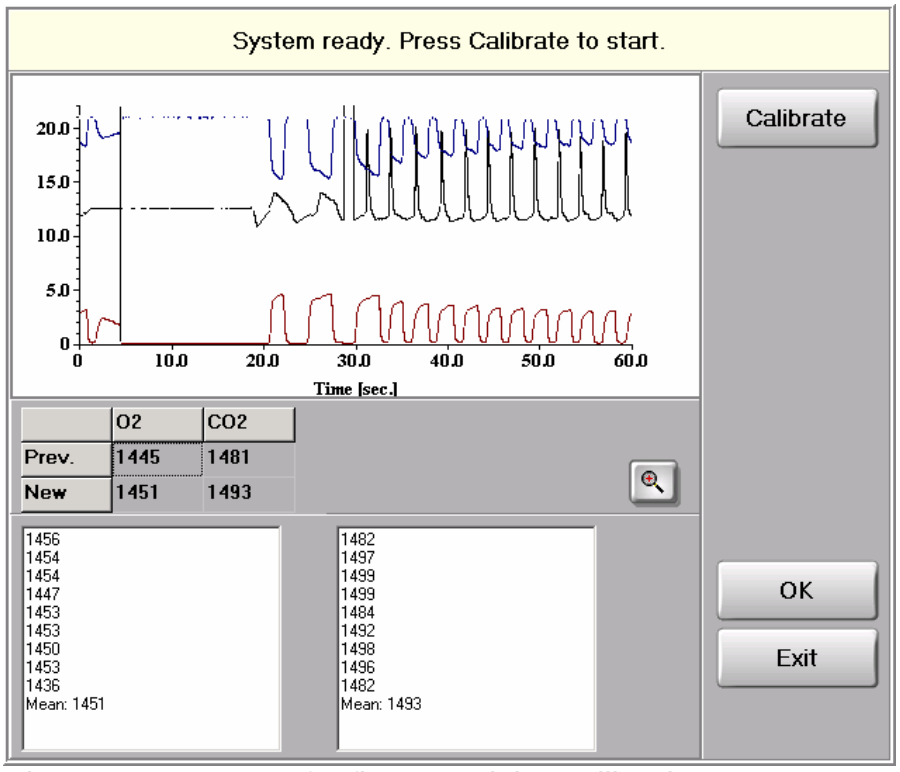


Figure 4.5.3-1 Menu for flow-gas delay calibration

4.6 GAS PRESSURE SENSOR OFFSET CALIBRATION

The gas pressure sensor measures the gas bottle pressure in bar.
The gain calibration is factory calibrated to 43.75 in C:\Innocor\Setup\GasSystem.ini:

```
[GasPressure]
Gain=43.75
```

The offset can be calibrated by the procedure:

- Turn the Innocor on
- Do not connect a gas bottle
- Enter the service program of Innocor
- Select **Misc**.
- Select **Pressure**
- Press **Offset** to calibrate the offset of the pressure sensor.

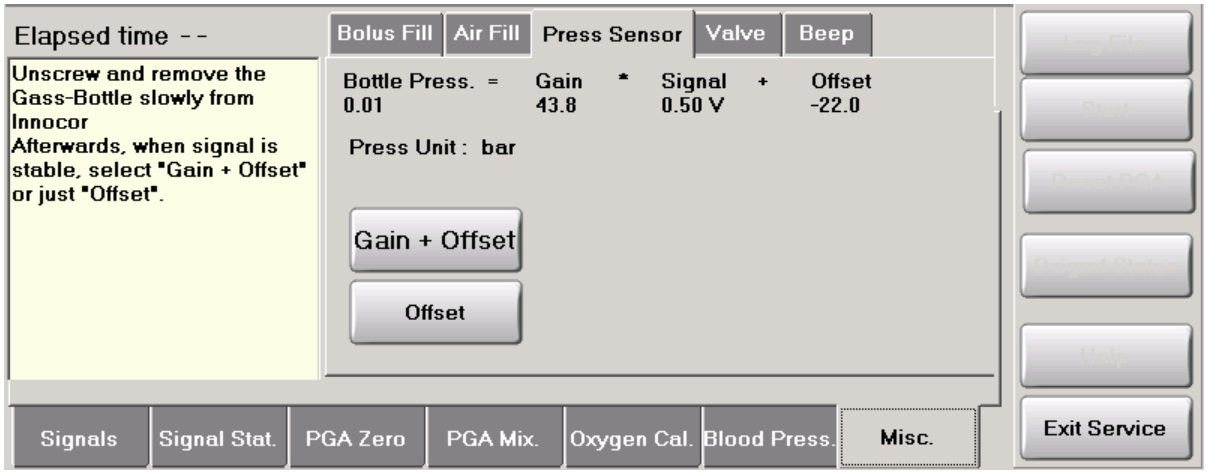


Figure 4.6-1 Menu for gas pressure sensor offset calibration

4.7 LEAK TEST ON GAS SUPPLY SYSTEM

The purpose of a leak test on the gas supply is to determine the leak rate in the gas supply system and to test that it is below the accepted limit.

4.7.1 Internal gas supply leak test

The internal leak test covers the parts of the gas supply located inside the Innocor, and the acceptance limit is 1 bar/hour, which corresponds to a leak rate of approx. 5 ml/hour.

- Turn the Innocor on
- Connect a gas bottle
- Enter the service program of Innocor
- Wait ½ hour to stabilise Innocor & gas bottle temperatures
- Select **Misc**.
- Select **Pressure**, see figure 4.6-1.
- Unscrew the gas bottle counter-clockwise 1½ turns
- Note, the gas bottle pressure
- Wait at least 1 hour
- Note, the gas bottle pressure again
- Calculate the leak rate per hour
- The leak rate is accepted if lower than 1 bar/hour
- In case of too high leak rate inspect:

  - The o-ring where the gas bottle is screwed down
  - The tubing internally in the Innocor
- If the leak rate is still too high, return the Innocor to Innovision for repair

4.7.2 Total gas supply leak test

The total leak test covers the leak rate of the gas supply when both of the pneumatic strings (Pneu 1 & 2) are activated. If the Innocor can pass the internal leak test, the total leak test will determine the leak rate of the RVU. The acceptance limit for the total leak rate is 10 bar/hour, which corresponds to a leak rate of approx. 50 ml/hour. The reason for the relative higher leak rate is a diffusion of gases through the wall of the silicone 6-tube.

- Turn the Innocor on
- Connect a gas bottle
- Connect the RVU
- Remove the insert, and close Pneu 1 and 2, or connect a tube between them.
- Enter the service program of Innocor
- Wait ½ hour to stabilise Innocor & gas bottle temperatures
- Select **Misc**.
- Select **Valve.**
- Press **RVU Blocked**, see figure 4.7.2-1.
- Select **Pressure**, see figure 4.6-1.
- Unscrew the gas bottle counter-clockwise 1½ turns
- Note, the gas bottle pressure
- Wait at least 1 hour
- Note, the gas bottle pressure again
- Calculate the leak rate per hour
- The leak rate is accepted if lower than 10 bar/hour
- In case of too high leak rate inspect (and the internal leak test is passed):
  - The tubing of the RVU
- If the leak rate is still too high, return the Innocor to Innovision for repair

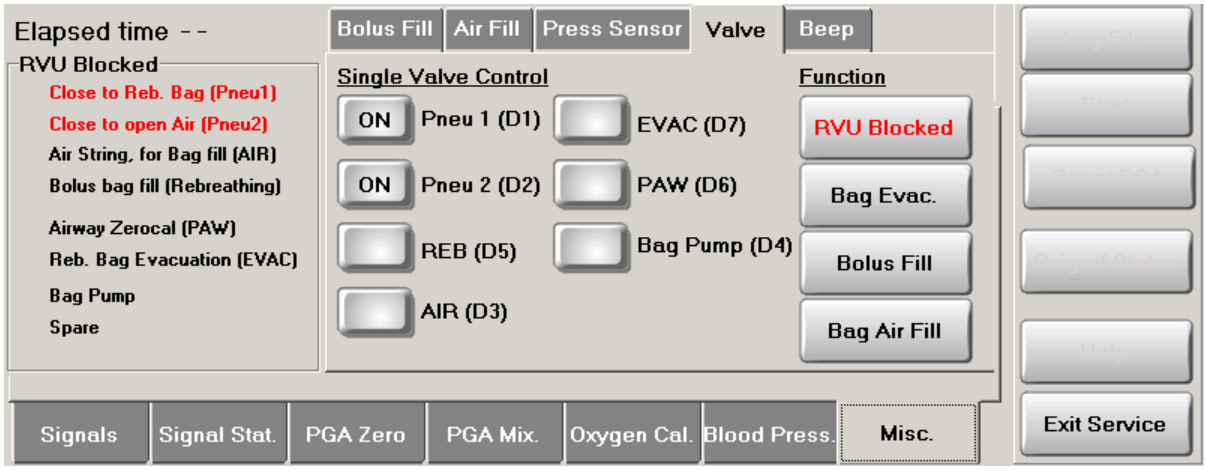


Figure 4.7.2-1 Menu for opening Pneu 1 & 2 during leak test

4.8 EVACUATION TEST

The purpose of making an evacuation test is to check the automatically detection of when the bag is empty and to check the evacuation flow.

4.8.1 Automatically detection of bag empty

- Enter the service program of Innocor
- Connect a gas bottle
- Connect a standard rebreathing bag to the RVU
- Select **Misc**.
- Select **Air fill**
- Enter test volume, e.g. 2000 ml
- Select test
- Check that the evacuation is automatically stopped when the bag is empty
- If not, a leak could be present in the evacuation line or the setting of the bag pressure sensor is drifted
- Inspect for leaks:
  - The tubes to the RVU
  - The bag connection
  - Internal tubing of the Innocor

4.8.2 Evacuation flow

- Enter the service program of Innocor
- Connect a gas bottle
- Connect a standard rebreathing bag to the RVU
- Select **Misc**.
- Select **Air fill**
- Enter test volume, e.g. 2000 ml
- Select **Test**
- Enter 2000 ml as measured volume in order not to change the air filling flow
- Select **Test** and measure the time to evacuate the bag.
- The evacuation flow is typical greater than 45 ml/sec
- If not, inspect:
  - The tubings to the RVU for occlusion
  - That the protection caps are removed from the back of the Innocor
- If still not acceptable, test the air filling flow to see if it is related to the air/evacuation pump. If the air filling flow is ok, the problem is probably in the separate evacuation line.

4.9 RVU TEST

A leak test of the RVU can be performed by inspecting the rebreathing curve after a test. If the CO_2 signal shortly drops significantly during the test, and the O_2 at the same time changes significantly against 20.95, a leak in the RVU is probably present. Note, that a missing nose clip or a high emptying pressure can also give signals drop on the CO_2 signal. A high emptying pressure can result in a drop in all the signals CO_2, SF_6 & N_2O, but not the O_2. If a high emptying pressure is causing drops in the gas signals, the reaction is immediately seen on the CO_2, SF_6 & N_2O signals. This means that the spikes/drops normally will be seen on the expiration part of the curve.

In case of a leak inspect that:

- The gas bottle pressure is higher than 5 bar
- The “balloon” in air / BbB port is fully inflated in order to block the port
- No visible leaks are present in the RVU or bag

If still not acceptable try to replace the RVU insert or gas inlet.

If this doesn’t help either, inspect the internal tubing of the Innocor.

4.10 REBREATHING TEST USING A SYRINGE

The purpose of making a rebreathing test using a syringe is to check the determination of the VL.

- Set the piston to 1½ litre on a 3 litre syringe
- Connect the syringe to the mouth port of the RVU
- Make a normal rebreathing using a bag volume of 1.5 litre (move the piston according to the target breathing frequency)
- Convert the calculated VL to ATP using the following formulae:
  $VL_{ATP} = VL_{BTPS}*(PB-47)/(PB-18*RH/100)*(273+t)/310$
  The VL_{ATP} is expected to be in the range 1.620 ±0.1litre without the flowmeter, and 1.680 ±0.1litre with the flowmeter.
- If not, check the air and bolus filling flow
- The calculated Vo_2 is expected to be within -0.167 ±0.1 l/min
- The calculated Qc is expected to be within ±0.3 l/min

4.11 CALIBRATION OF TOUCH SCREEN

If the touch screen is out of sync try to make a calibration of the touch screen.

- Exit to windows (On the Innocor main screen press right-top corner followed by left-top corner).
- Select **Shortcut**
- Double click on the **Elo calib** program
- Press the **Calibrate** button and follow the instructions on the screen

4.12 CALIBRATION OF NIBP

The calibration of the NIBP module can only be performed at Innovision, or by qualified trained personnel. It is recommended to have the NIBP module checked routinely, e.g. 1 time a year.

5 TROUBLESHOOTING

5.1 REBREATHING CURVES

The rebreathing curves generated during a test are valuable during troubleshooting of the Innocor. In this section some typical curves will be shown and explained, followed by some typical errors.

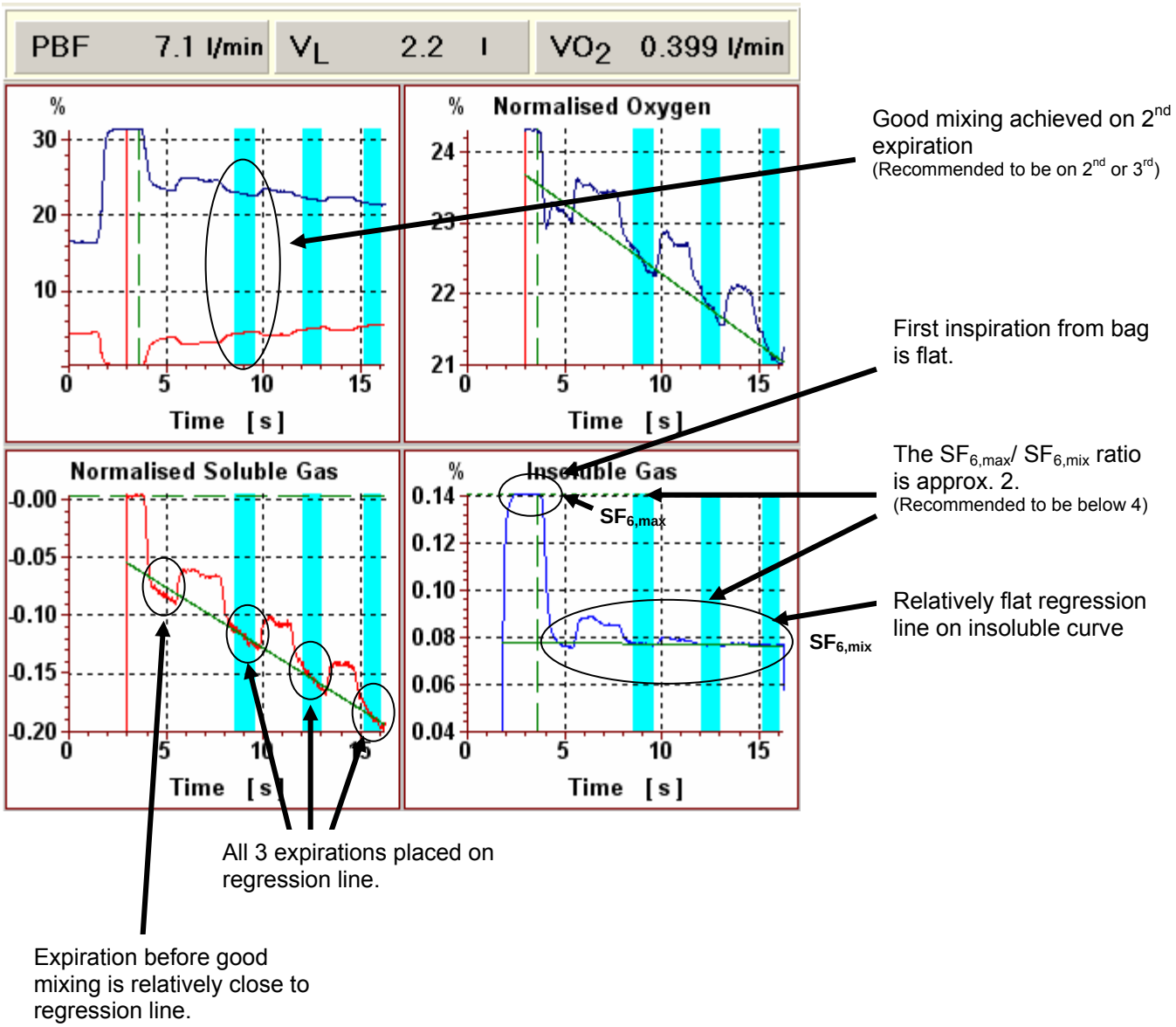


Figure 5.1-1 Normal rebreathing curves

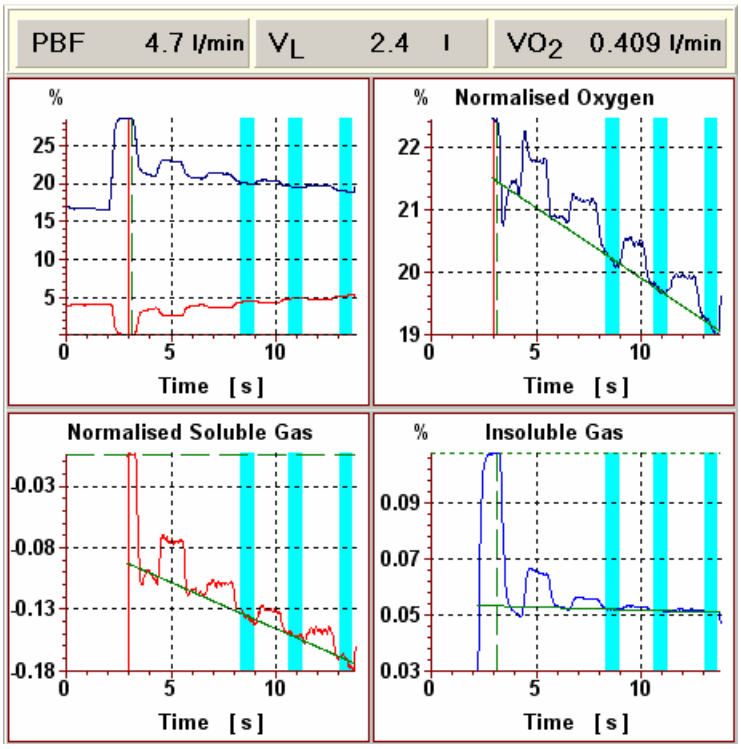


Figure 5.1-2 Normal rebreathing curves at rest

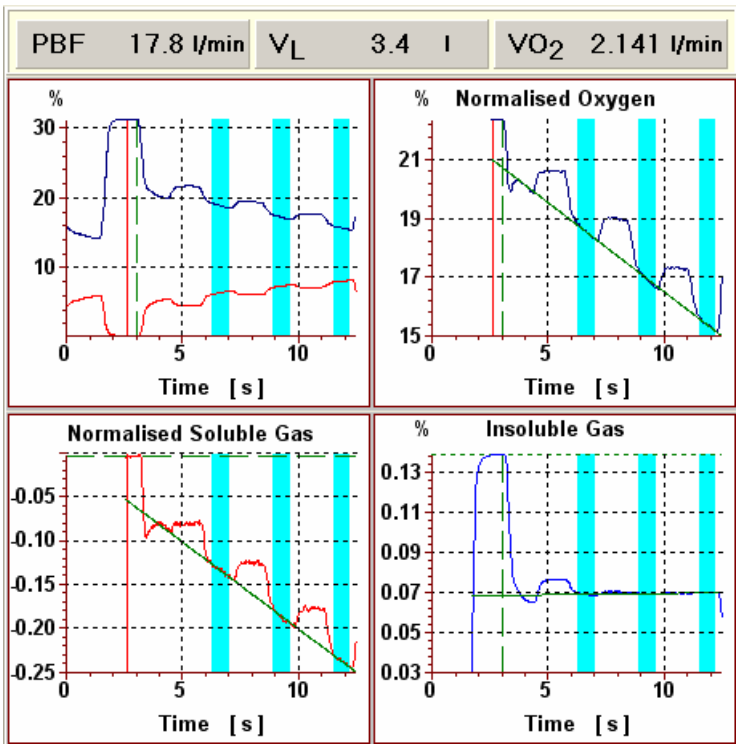


Figure 5.1-3 Normal rebreathing curves

Failure: the dilution of the bag is too high.

$SF_{6,max}$ is approx. 8 times higher than the $SF_{6,mix}$.

Solution: Instruct the subject to expire a little more at the last expiration before the first inspiration from the bag, or increase the bag volume

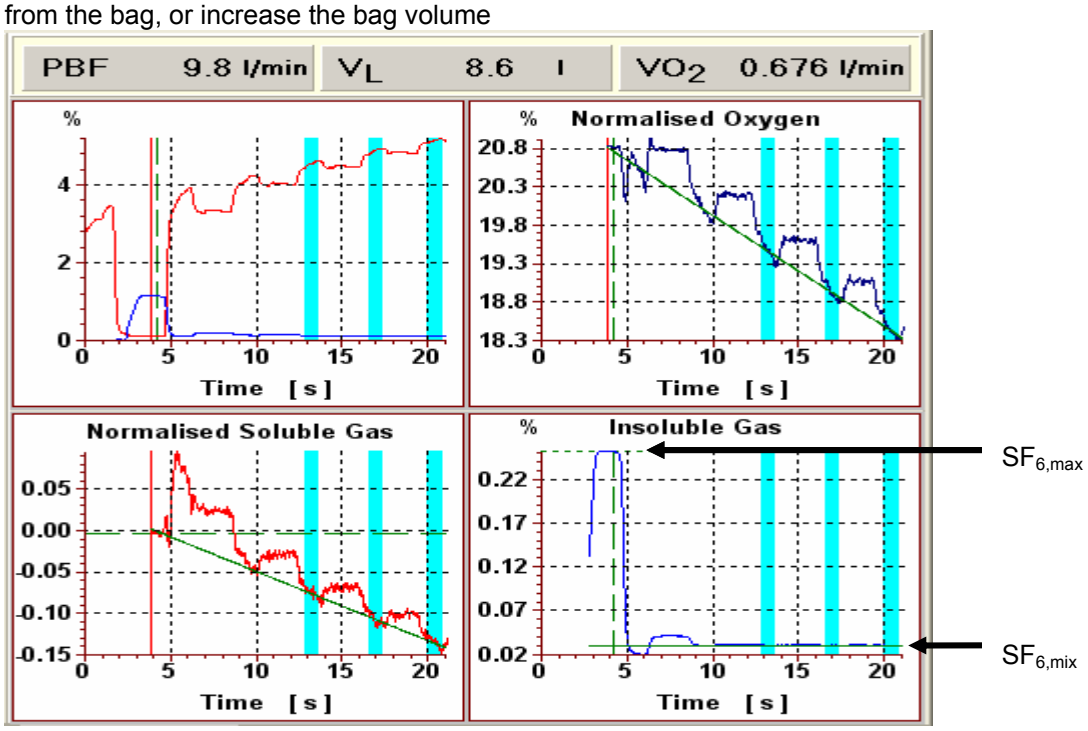


Figure 5.1-4 Rebreathing curve with a too high dilution of the bag.

Failure: the mixing of the insoluble gas is very slow.

The software starts to use the data on the 7th expiration despite accurate mixing is not achieved. The mouth piece pressure (MPP) is seen to be weak, because the subject is not emptying the bag at each inspiration.

Solution: Instruct the subject to empty the bag at every inspiration and/or instruct the subject to expire a little more at the last expiration before the first inspiration from the bag.

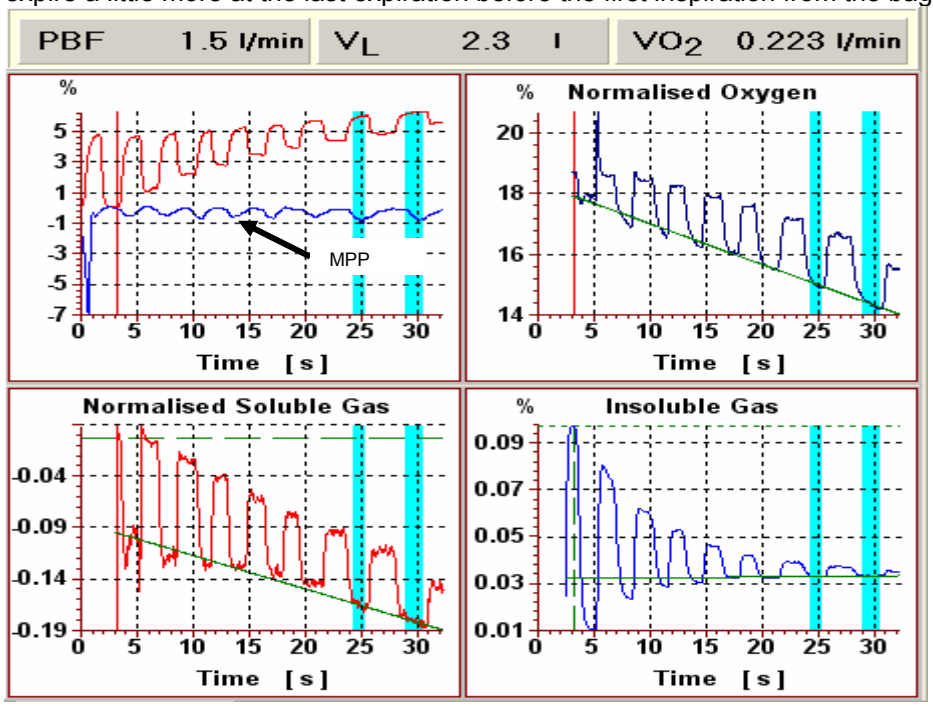


Figure 5.1-5 Rebreathing curves with a slow mixing

Failure: the mixing of the insoluble gas is very slow.

The software starts to use the data on the 6th expiration. The mouth piece pressure (MPP) is seen to be weak, - the subject is not emptying the bag at the first 3 inspiration.
Solution: Instruct the subject to empty the bag at every inspiration.

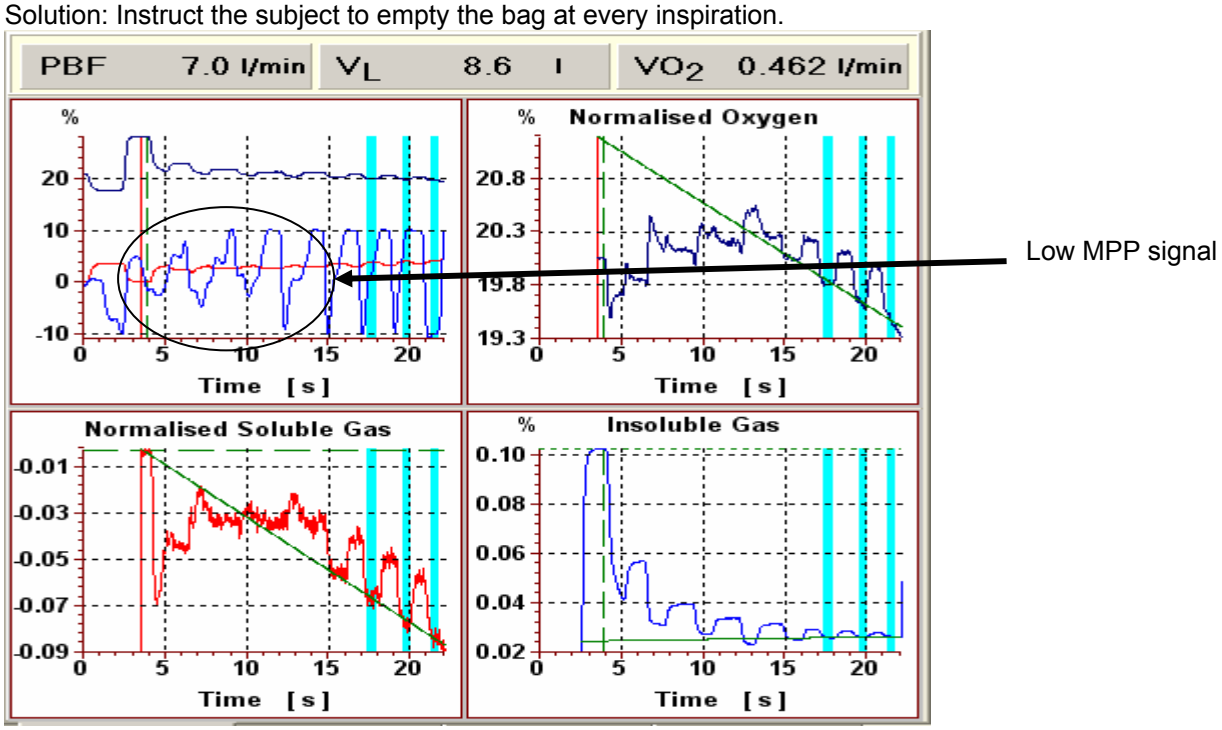


Figure 5.1-6 Rebreathing curves with a slow mixing

Failure: A spike is present on all the gases at the end of the first 4 inspirations.

The spike on O_2 is going up against the ambient concentration (20.93%), while the spikes on the other gases are going down to 0%. The reason for the spikes is because the RVU or sample line is leaking.
Solution: Repair the RVU or sample line

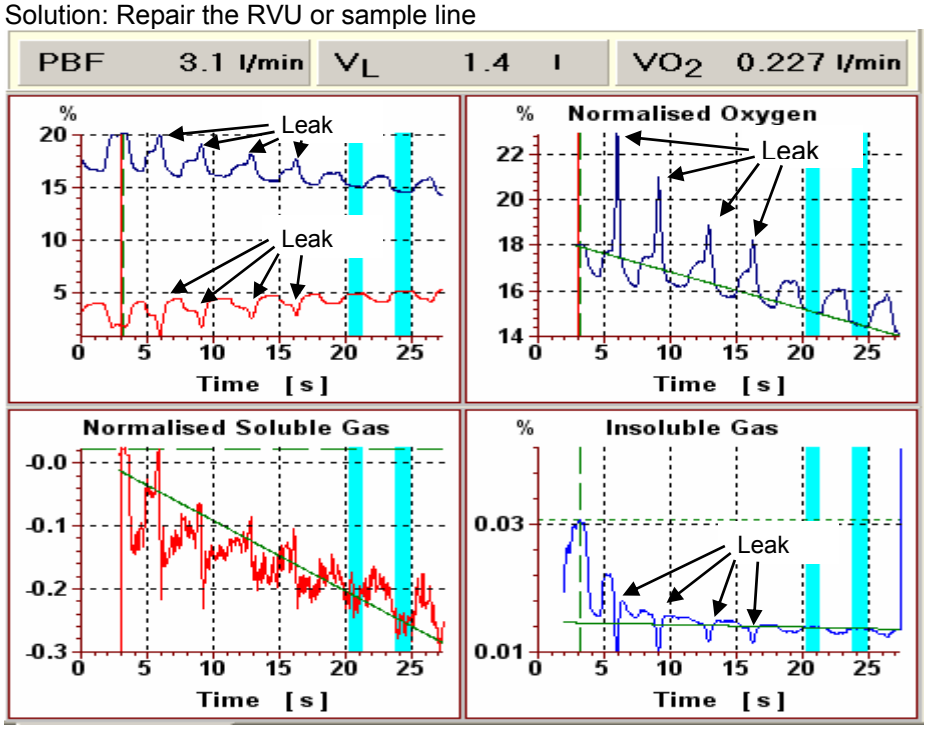


Figure 5.1-7 Rebreathing curves with leak

Failure: A spike is present on all the gases at the end of the 3rd inspiration (except on the raw O_2).

The spikes on the gases are going down to 0%. The reason for the spikes is a too high negative pressure when the bag is emptied, in which case the gas analyser can fail. Note that the spike is not present on the raw O_2 signal – only on the normalised O_2 signal because of the normalisation against the insoluble gas, which has a negative going spike. The spike is NOT a leak.
Solution: Instruct the subject to empty the bag, but without unnecessary pressure.

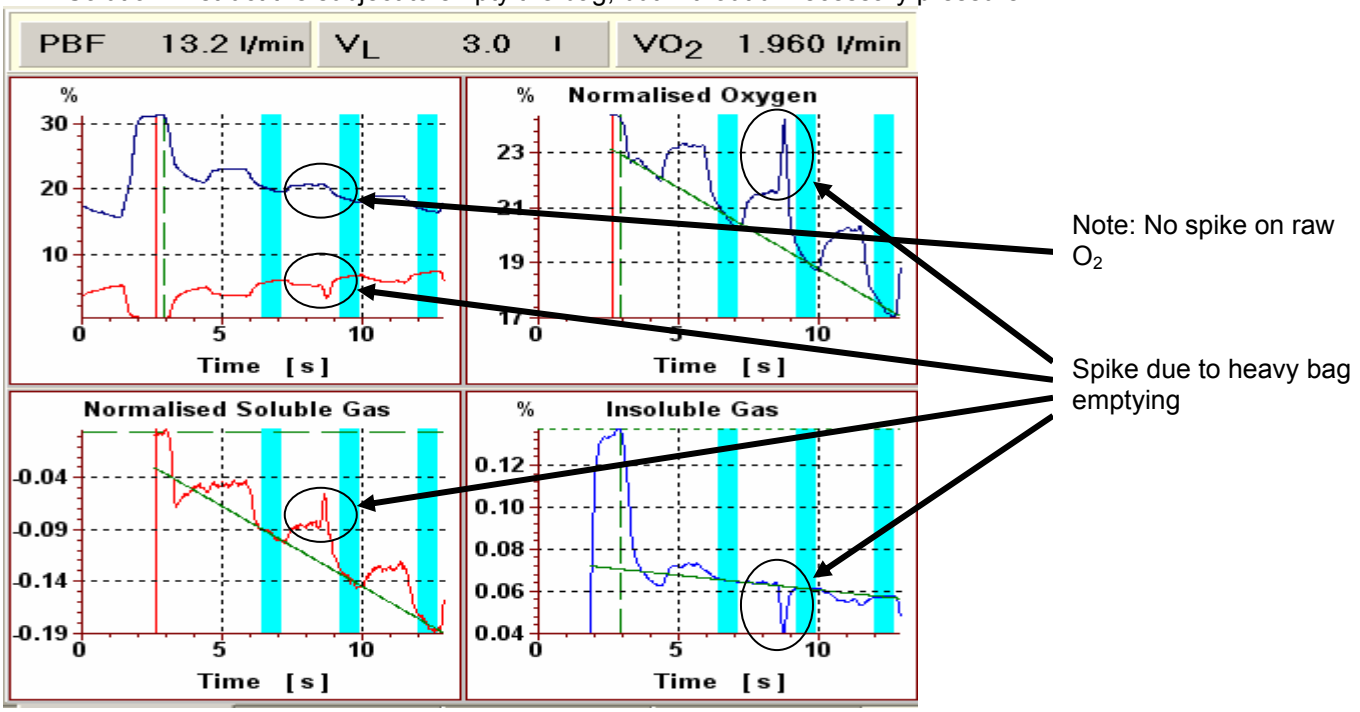


Figure 5.1-8 Rebreathing curves with spikes

Failure: The rebreathing frequency is very low.

The first breath is at 8 /min, the second and third at 12 /min. (Minor spikes is also presents).
Solution: Instruct the subject to breathe faster.

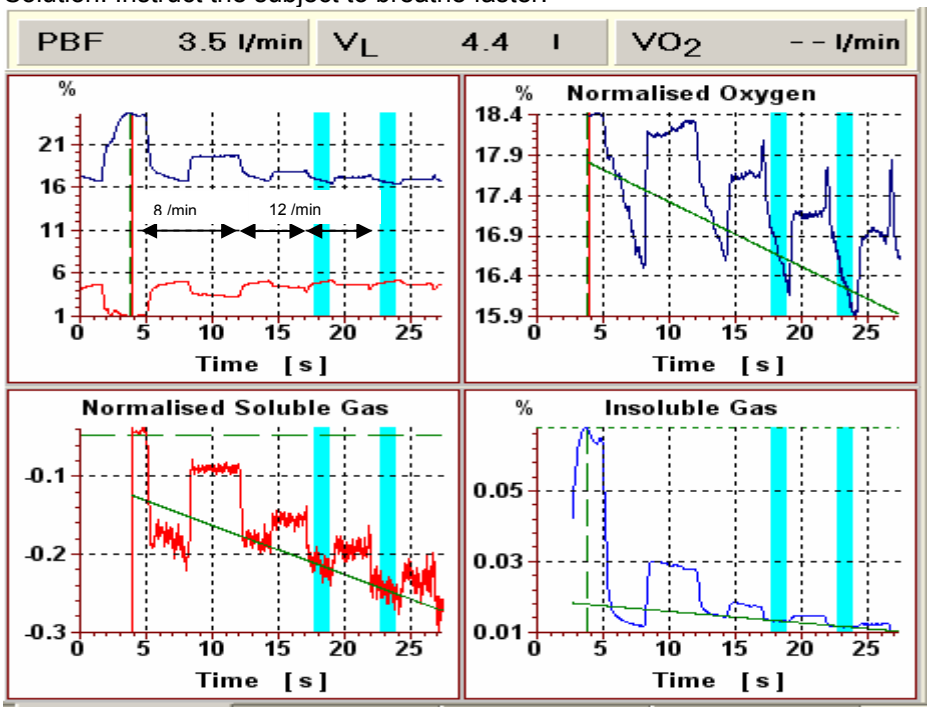


Figure 5.1-9 Rebreathing curves with a low respiration rate

Failure: The oxygen signal is missing.

The detection of expiration is based on the missing oxygen signal and fails.
Solution: Repair the oxygen sensor (Oxigraf). The "Expiration based on" can be set to CO_2 until the oxygen sensor is repaired.

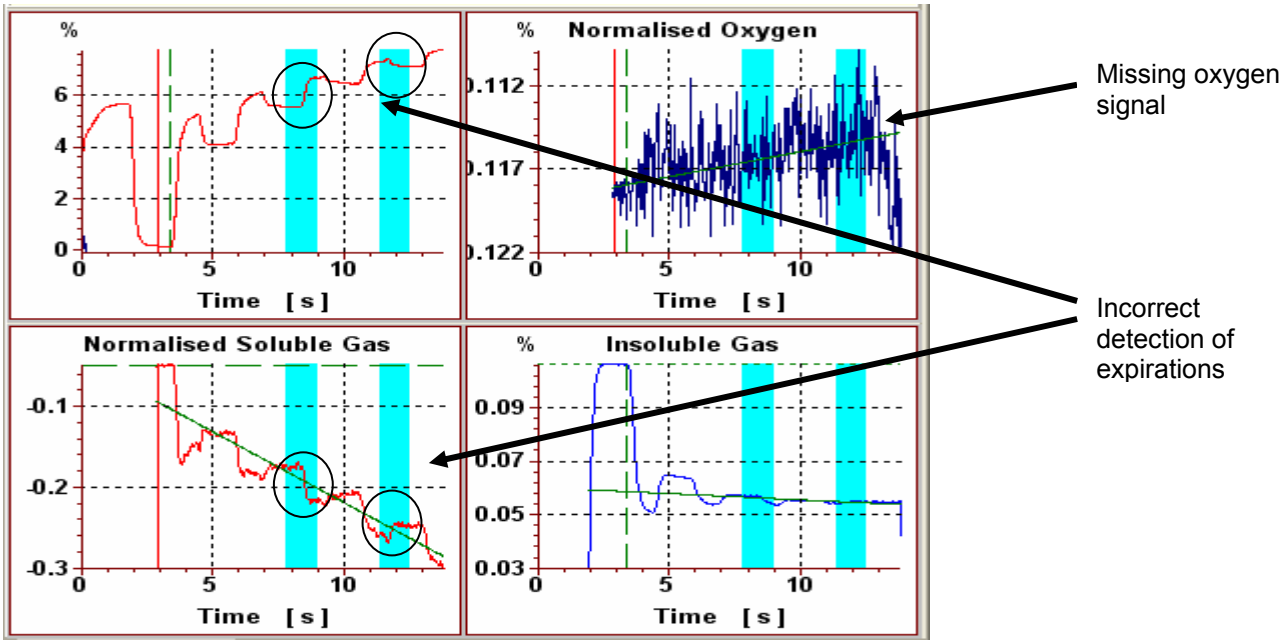


Figure 5.1-10 Rebreathing curves with a missing oxygen signals

Failure: The bolus and air is not mixed well in the rebreathing bag.

The detection of the SF_6 concentration in the bag – based on the max value – fails. This will overestimate the V_L, and thereby the PBF, CO and Vo_2.
Solution: Check that the bag is free floating during filling, and that the filling tube is correctly mounted.

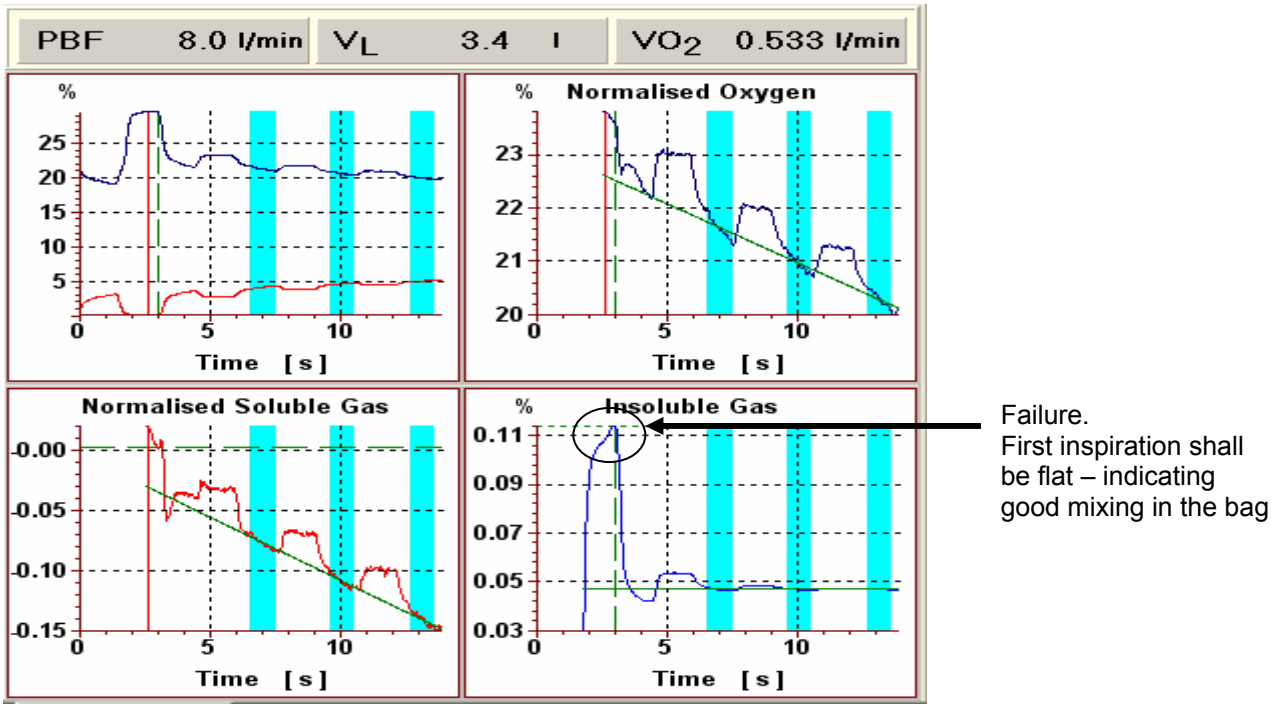


Figure 5.1-11 Rebreathing curves with an initial bad mixing of the bag.

Failure: The background on the soluble gas is too high due to recirculation and/or missing washout of the lungs between 2 tests.
Solution: Wait a little longer between tests. It is recommended to wait at least 5 minutes at rest, and down to 3 minutes at higher exercise.

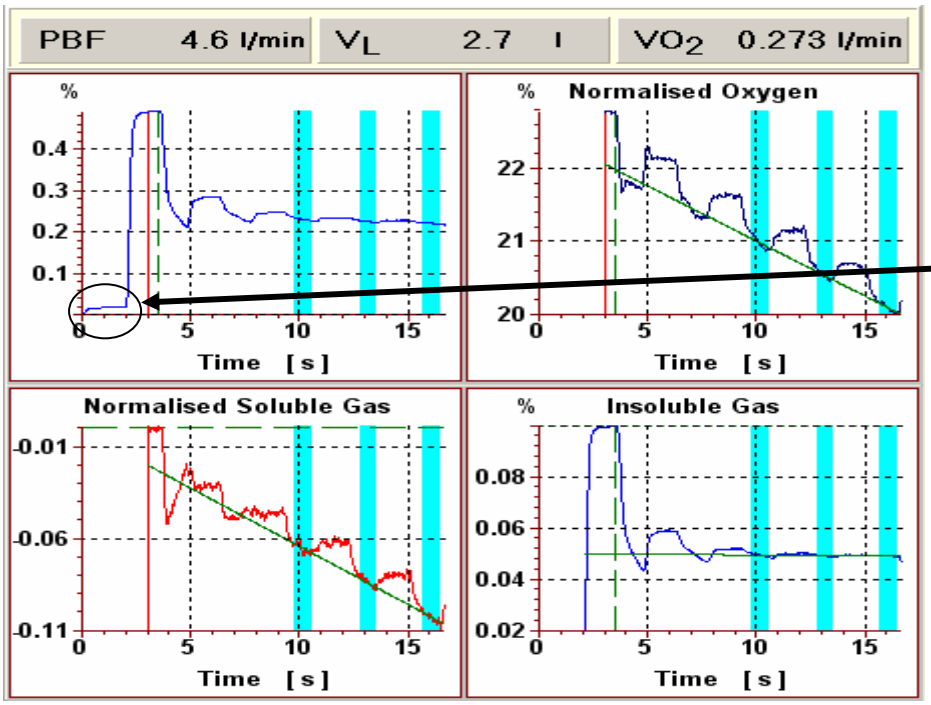


Figure 5.1-12 Rebreathing curves with a high background on the soluble gas.

5.2 GAS SUPPLY SYSTEM / GAS BOTTLE SYSTEM

Symptom	Cause	Recovery
No gas bottle pressure reading	No power to I/F Board	Inspect power cabling to I/F Board internally in the Innocor
No gas bottle pressure reading	Failure on analogue cable from pressure sensor	Inspect analogue cable from pressure sensor to IF board
No gas bottle pressure reading	Failure on analogue cable from PGA to IF board (optional via BBB sensor electronics)	Inspect analogue cable from PGA to IF board (Item 39 / CAB00018)
No sound from inlet pump	Inlet pump defect	Return Innocor to Innovision for replacement of inlet pump
No sound from inlet pump	Connector to inlet pump defect	Inspect/replace connector to inlet pump
No inlet flow	Inlet pump defect	Return Innocor to Innovision for replacement of inlet pump
No inlet flow	Tubing to inlet pump defect	Inspect/replace tubing from gas sample line to inlet pump through PGA and oxigraf
No inlet flow	Acoustic Attenuator defect	Inspect/replace Acoustic Attenuator (Item 18 / SUB00033)
Bolus filling flow too low / too high	LP regulator out of calibration or defect	Adjust LP regulator (see section 4.2.1) or return Innocor to Innovision for replacement of flow regulator
Bolus filling flow depending on gas bottle pressure	Defect LP regulator	Return Innocor to Innovision for replacement of flow regulator
Gas leaking out of Pneu1 on six tube when Innocor is not powered and RVU disconnected	Defect Pneu1 valve	Replace valve (SOL0003)
Gas leaking out of Pneu2 on six tube when Innocor is not powered and RVU disconnected	Defect Pneu2 valve	Replace valve (SOL0003)
Gas leaking out of RB/air on six tube when Innocor is not powered and RVU disconnected	Defect RB/air valve	Replace valve (SOL0003)
Bottle warning	No gas	Connect a new bottle

5.3 REBREATHING MANOEUVRE

Symptom	Cause	Recovery
Evacuation does not stop / start	Bag pressure sensor defect	Return Innocor to Innovision for replacement of bag pressure sensor
Evacuation does not stop	Bag pressure line leaking / not connected to sensor	Inspect tubing internally in the Innocor
Evacuation does not stop	Bag port not closed/inflated	Check gas bottle pressure
Evacuation does not stop	RVU leaking – insert defect	Change insert or RVU

Symptom	Cause	Recovery
Cannot trig on MPP signal	Occluded MPP tube (ref.)	Inspect tubing external / internally in the Innocor
Cannot trig on flow signal	Missing flow signal	Check flowmeter and external / internal tubing in the Innocor
Inspiration / expiration message reversed	Wrong setup or flowmeter mounted incorrectly	Check Hardware.ini [MPP] Sign=1 (without flowmeter) Sign=-1 (with flowmeter)
Evacuation does not stop and is not emptying the bag	Evac. or Air string valve defect	Replace valve(s) (SOL0003) or return Innocor to Innovision

5.4 GAS SIGNALS

Symptom	Cause	Recovery
No signal on CO_2, N_2O, SF_6 & O_2	Gas inlet not connected or defect	Check or replace gas inlet
No signal on CO_2, N_2O, SF_6 & O_2	Inlet pump defect	Return Innocor to Innovision for replacement of inlet pump
No signal on CO_2, N_2O, SF_6 & O_2	Connector to inlet pump defect	Replace connector or return Innocor to Innovision
Digital O_2 is OK, but not the analogue O_2	Failure on analogue cable from Oxigraf to PGA	Inspect analogue cable from Oxigraf to PGA (Item 36 / CAB00003)
Slow response on signals	Partly occluded particle filter	Change particle filter
First inspiration not flat	Partly occluded particle filter	Change particle filter
First inspiration not flat	Rebreathing gas not mixed properly	Check bag is free floating, check end of filling tube to bag or use a smaller bag.
Low/High insoluble gas concentration	LP regulator out of calibration	Adjust LP regulator (see section 4.2.1)
Low/ High insoluble gas concentration	Bolus filling flow out of calibration	Adjust bolus filling flow (see section 4.2.1)
Low/ High insoluble gas concentration	Air filling flow out of calibration	Adjust air filling flow (see section 4.2.4)
Low insoluble gas concentration	Partly occluded particle filter	Change particle filter
Low insoluble gas concentration	No more gas	Check gas bottle. e.g. connect a new bottle
Low insoluble gas concentration	Bolus valve not opening	Return Innocor to Innovision for replacement of bolus valve.
Low insoluble gas concentration	The bag opening is triggered during expiration	Instruct patient not to stop breathing out during expiration
High insoluble gas concentration / narrow first inspiration	Bag is not mixed properly, “filling line” off	Connect “filling line” or shake the bag prior to the rebreathing
High insoluble gas concentration	Bolus valve not closing	Return Innocor to Innovision for replacement of bolus valve
High/Low insoluble gas concentration	Incorrect calibration	Re-calibrate PGA
Small spikes on O_2	Missing particle filter	Connect particle filter
Noisy signals	Defect flow regulation	Check the FFT spectrum at 50 Hz, if wide change tubing
No signal on CO_2, N_2O & SF_6, but O_2 OK	Chopper wheel not turning	Check the FFT spectrum – (peaks at 214.8, SF_6, 273.4, CO_2, 332, N_2O)

Symptom	Cause	Recovery
No signal on CO_2, N_2O & SF_6, but O_2 OK	IR source not powered	Check the FFT spectrum – (peaks at 214.8, SF_6, 273.4, CO_2, 332, N_2O)
No signal on N_2O & SF_6, but CO_2 & O_2 OK	No more gas	Check gas bottle. e.g. connect a new bottle
CO_2 abnormal during test	No more gas – balloons not inflated	Connect a new bottle
Down going spikes on CO_2, N_2O & SF_6, but not on O_2	Too high evacuation pressure when patient empties the bag	Instruct patient to apply lower under pressure during emptying the bag
Down going spikes on CO_2, N_2O, SF_6 & O_2	Patient not using nose-clip	Instruct patient to use nose-clip
Down going spikes on CO_2, N_2O, SF_6 & O_2	Gas inlet defect	Change gas inlet
Down going spikes on CO_2, N_2O, SF_6 & O_2	RVU balloon to ambient air not inflated completely due to too low LP pressure	Adjust LP regulator (see section 4.2.1) or return Innocor to Innovision for service
Spikes on CO_2, N_2O, SF_6 & O_2	RVU leaking – insert defect	Change insert or RVU
O_2 goes down every 1-2 seconds	Failure on line-scan in the Oxigraf	Try a longer warm up of the Innocor
O_2 goes down to 0 during test	Beep support is enabled on an Innocor which does not support beep, but instead resets the Oxigraf	Turn beep off in setup or disable beep support in Hardware.Ini file.

5.5 RESULTS

Symptom	Cause	Recovery
Incorrect FRC, Qc, Vo_2, etc.	Incorrect calibration	Re-calibrate PGA
No or incorrect BP measurement	NIBP cuff not correct positioned on patient	Correct cuff position on patient according to figure 2.5.5-1
No or incorrect BP measurement	Incorrect size of NIBP cuff	Change cuff to correct size
No or incorrect BP measurement	Too much movement of arm during measurement	Instruct patient to keep arm quite during NIBP measurement
Expiration detection fails	Delay on O_2 and/or PGA gases incorrect	Correct delay via PGAMON program: 1982 – O_2 delay = 325 1974 – CO_2 delay = 0 1973 – N_2O delay = 30 1975– SF_6 delay = 0
Unstable HR / SpO_2	Too much movement of the finger clips during test	Tape the line to the hand
No HR during BP measurement	NIBP cuff and pulse oximeter cuff on same arm	Place pulse oximeter sensor on other arm, or complete the BP measurement before

5.6 RVU

Symptom	Cause	Recovery
Valve is not clicking (opening)	No power to I/F Board	Inspect power cable to I/F Board
High resistance during inspiration (only Hans Rudolph RVU)	Ring missing on the dynamic restrictor on the RVU	Insert missing ring, or lift up the restrictor 5 mm
Ports not inflated	Defect LP regulator or wrong setting	Adjust pressure up (see section 4.2.1)
Balloons jumps off (only Hans Rudolph RVU)	Defect LP regulator	Adjust pressure down (see section 4.2.1)

5.7 SCREEN / TOUCH

Symptom	Cause	Recovery
Screen is black after power on	No power to SBC	Check mains & check fuses. Inspect power cable to SBC internally in the Innocor
Screen is white after power on	Not enough power to SBC	Check power connector
No reaction on touching the buttons on the screen	Failure on cables to touch screen controller	Inspect cabling internally in the Innocor (Item 7, 27 & 49)
No reaction on touching the buttons on the screen	Out of calibration	Recalibrate touch (See section 4.11)

5.8 PGA

Symptom	Cause	Recovery
PGA not responding	No power to PGA	Inspect power cable to PGA internally in the Innocor
PGA not responding	Failure on RS232 cable to PGA	Inspect RS232 cabling internally in the Innocor
PGA not responding	Loose Eprom on PGA	Press on Eprom located just below power connector to IF board

5.9 OXIGRAF

Symptom	Cause	Recovery
No response from Oxigraf	No power to Oxigraf	Inspect cable to Oxigraf internally in the Innocor
No response from Oxigraf	Failure on RS232 cable to Oxigraf	Inspect RS232 cabling internally in the Innocor
Oxigraf not ready	Failure on line-scan in the Oxigraf	Try a longer warm up of the Innocor

5.10 PULSE OXIMETER

Symptom	Cause	Recovery
Unstable HR / SpO_2	Too much movement of the finger clips during test	Tape the line to the hand or use Nonin Flex system (8000J Adult Flex Sensor)
No HR and SpO_2 signals – pulse oximeter not responding	Failure on RS232 cable to pulse oximeter	Inspect RS232 cabling internally in the Innocor
No HR during BP measurement	NIBP cuff and pulse oximeter sensor on the same arm	Place pulse oximeter sensor on the other arm, or complete the BP measurement before starting the rebreathing

5.11 NIBP

Symptom	Cause	Recovery
No or incorrect BP measurement	NIBP cuff not correct positioned on patient	Correct cuff position on patient according to figure 2.5.5-1
No or incorrect BP measurement	Incorrect size of NIBP cuff	Change cuff to correct size
No or incorrect BP measurement	Too much movement of the arm during measurement	Instruct the patient to keep the arm quite during NIBP measurement
No response from NIBP	No power to NIBP module	Inspect NIBP cabling internally in the Innocor
No response from NIBP	Failure on RS232 cable to NIBP module	Inspect NIBP cabling internally in the Innocor
Message: “Safety timeout”	Internal timer of NIBP module has detected a timeout due to too long time on a high cuff pressure	Reset NIBP timer by power off the Innocor, and power it on again.

5.12 PRINTER

Symptom	Cause	Recovery
Cannot print out	Printer not connected	Connect printer to USB port, or if printing is performed via the LAN, connect the Innocor to the LAN
Cannot print out	Printer not powered on	Power printer on
Cannot print out	Printer driver not installed	Install printer
Cannot print out	Actual printer is not the default printer	Set actual printer to the default printer: - Select control panel - Select printers - Right click on actual printer - Set use as default
Printer status is ready and document is waiting for printing, but is not printing.	Windows XP?	Disconnect printer at USB port, and reconnect printer.

5.13 SOFTWARE

Symptom	Cause	Recovery
Running scandisk at bootup	Innocor has not been shut down via the Innocor software	Use the Exit in the Innocor software to shut down the Innocor
Program execution stops during filling / emptying	HDU sensitive to pump vibrations	Inspect damping of air/evacuation pump

6 ERROR / WARNING MESSAGES

Code	Message	Cause	Recovery
0101	Only 2 breaths are included in the analysis. Breathe faster or increase rebreathing time.	Only 2 breaths are included in the analysis. 2 or less breaths rejected. 2 breaths used in calculation.	Breathe faster or increase rebreathing time.
0102	Too few breaths. Only 2 breaths are included in the analysis. Breathe faster or increase rebreathing time.	Only 2 breaths are included in the analysis. Original: 2 breaths rejected. 1 breath valid for calculation. Re-calculated using the last 2 breaths.	Breathe faster or increase rebreathing time.
8103	Too few breaths. Unable to calculate.	2 breaths rejected. 0 breath valid for calculation or 1 or 0 breath rejected 1 or 0 breath valid for calculation	Breathe faster or increase rebreathing time.
0104	Slow mixing. Check that bag is emptied at the end of each inspiration.	3 or more breaths rejected. 3 or more breaths used in calculation.	Empty bag at the end of each inspiration.
0105	Slow mixing. Only 2 breaths are included in the analysis. Check that bag is emptied at the end of each inspiration.	Only 2 breaths are included in the analysis. 3 or more breaths rejected. 2 breaths used in calculation.	Empty bag at the end of each inspiration.
0106	Bad mixing. Only 2 breaths are included in the analysis. Check that bag is emptied at the end of each inspiration (Recalculated using the last 2 breaths).	Only 2 breaths are included in the analysis. Original: 3 or more breaths rejected. 1 or 0 breath valid for calculation. Re-calculated using the last 2 breaths.	Empty bag at the end of each inspiration.
0107	High insoluble gas concentration.	See section 5.4.	
0108	Low insoluble gas concentration.	See section 5.4.	
0109	Insoluble gas is not found.	Raw data file corrupted.	
010A	Soluble gas is not found.	Raw data file corrupted.	
010B	High background on soluble gas.	Soluble gas is not washed out from previous test.	Increase time between tests. At rest 5 minutes are enough – during exercise a shorter period is accepted.
010C	Mouth piece pressure signal not found.	Raw data file corrupted.	
010D	Test stopped due to high CO2 level.	CO_2 concentration during test exceeded max CO_2 limit defined in the setup.	Increase bag-volume, breathing frequency or max CO_2 limit.
010E	Test stopped due to low O2 level.	O_2 concentration during test dropped below min O_2 limit defined in the setup.	Increase bolus fraction, bag-volume, breathing frequency or reduce min O_2 limit.
010F	Test stopped due to exceeding Max rebreathing	Rebreathing test could not be completed within the	Increase breathing frequency or max

	time.	maximum rebreathing time defined in the setup.	rebreathing time.
	Gas analyser not ready. Further measurement not possible.	See section 5.8.	
	Gas analyser not installed.	PGA not configured to be installed in Hardware.ini	Check hardware.ini. See Innocor Software User Manual (COR-SUM-0000-001)
	Error in software version format.	Software code for new software is not correct.	Check serial number of Innocor and contact Innovision.
	Gas analyser code conflict.	New software not installed correctly.	Contact Innovision.
	Only ID below 2147483647 is valid. Contact your vendor to update patient database.	Database version is an older version and can only support numbers. The new database can support numbers and characters.	Use as it is, or send the database to Innovision in order to update it.
	Cannot update database because I.D. already is in use.	The database requires a unique ID number for each patient.	Use another ID.
	Graphically data not found	Corresponding raw data file has been deleted.	
	The old patient database was not found. A new empty patient database has been created!	No patient database exist	Restore a backup or continue with an empty one.
	The old experiment database was not found. A new empty experiment database has been created!	No experiment database exists.	Restore a backup or continue with an empty one.
	The print-setup file was not found:	The file PrintSetup.ini is missing.	See Printer Setup in Innocor Software User Manual (COR-SUM-0000-001)
	The pulse oximeter was not found!	See section 0.	
	The blood pressure unit was not found!	See section 5.11.	
	The Keyboard code was not found. Default keyboard is used.	Keyboard definition missing in language file (LanguageId)	See Language Support in Innocor Software User Manual (COR-SUM-0000-001)
	The Keyboard code was invalid. Default keyboard is used.	Invalid keyboard definition in language file (LanguageId).	See Language Support in Innocor Software User Manual (COR-SUM-0000-001)
	The Gas Cylinder data was not found. Further measurement not possible.	The database containing Gas Cylinder data is missing.	Contact Innovision.
	The Gas Cylinder number is invalid. Further measurement not possible.	The database containing Gas Cylinder data is invalid or corrupt.	Contact Innovision.
	The Gas Cylinder number is invalid.	The entered Gas Cylinder number is not a valid number.	Contact Innovision.

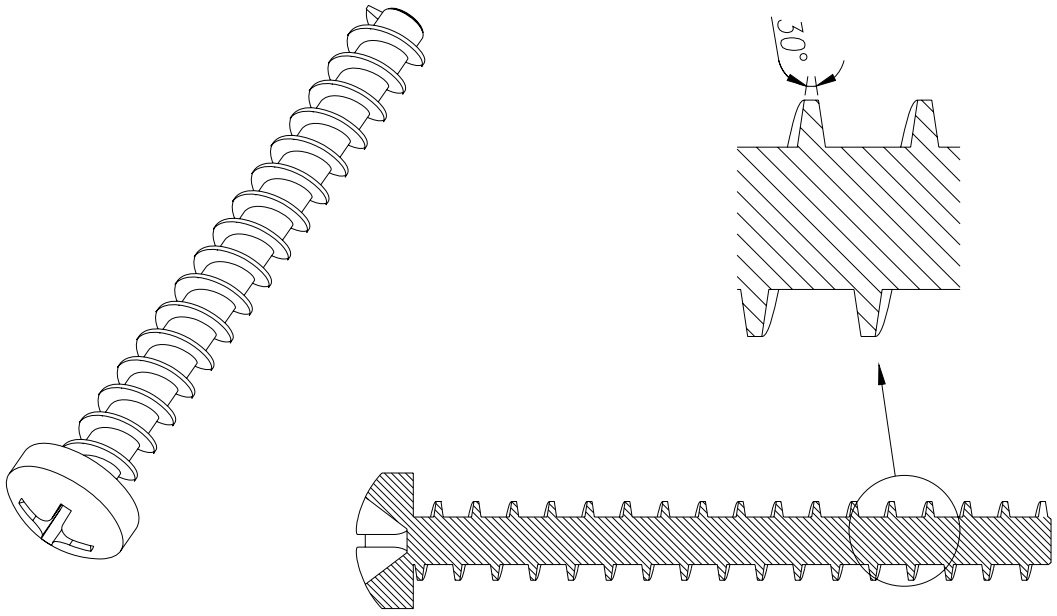
7 DISASSEMBLY AND REASSEMBLY

7.1 GENERAL SERVICE INFORMATION

7.1.1 Screws for thermoplastics

Special screws for thermoplastics are used to attach the rear and front part to the bottom part of the main housing. When using these screws, special considerations must be taken.

Description of screws for thermoplastics

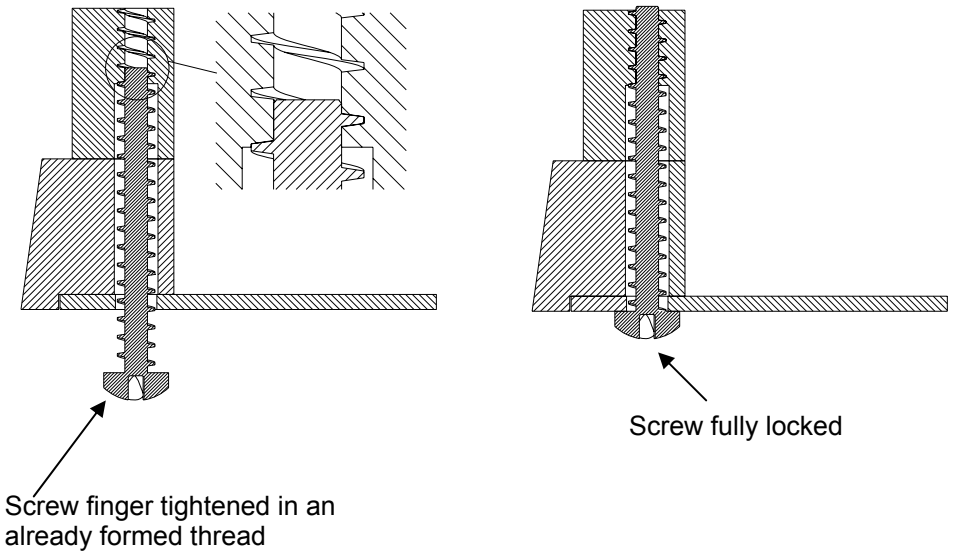


The screws for thermoplastic used in Innocor belong to a sort of so-called thread forming screws. This means that the first time the screw is inserted a thread is formed.
With the sharp 30º angle, the thread is easily penetrating the thermo plastic. The big thread elevation gives a high margin of safety against over tightening,

How to mount a screw for thermo plastic

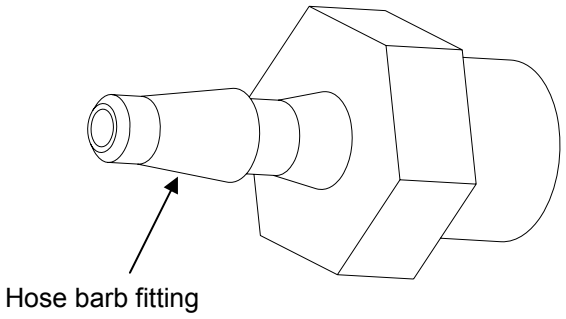
If a screw is inserted into a hole with an already formed thread, care must be taken not to form a new thread on top of the old one. Two threads in the same hole can result in a structural failure.

An "old" thread can be caught by first finger tightening the screw (approx. half a turn clockwise). A screwdriver can then be used to fully lock the screw.



7.1.2 Flexible tubing

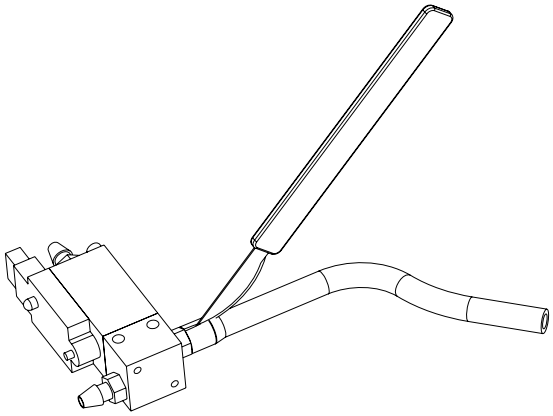
Flexible tubing is, if used correctly, very reliable and easy to use. If used in combination with a hose barb fitting, it also offers a relatively high operational pressure.



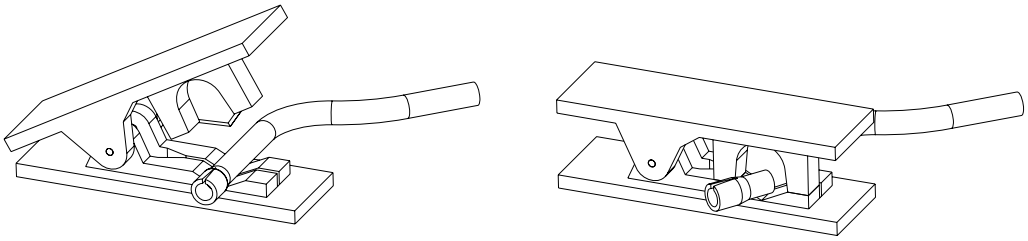
How to ensure leak proof connections

By following the step-by-step instruction below, leak tightness can be achieved in most cases.

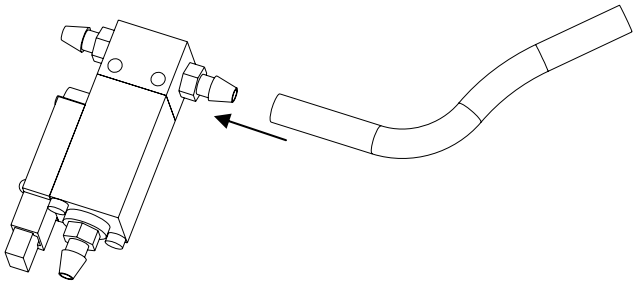
1. Disconnect the faulty component using a scalpel



2. Cut off the deformed part of the flexible tubing using the Tube Cutter.



3. Connect the new component using your fingers only!



7.2 CABINET

To disassembly the cabinet perform the following steps:

1) Remove gas bottle.
2) Disconnect power.
3) Unscrew the 2 nylon screws at the handle -see figure 7.2-1.
4) Unscrew the 8 screws at the bottom of the Innocor - see figure 7.2-1. Note, the 2 screws near the gas cylinder interface are longer than the others, and that the 2 screws at front are shorter.
5) Tip the LCD screen gently forward, and place it on foam in order not to damage the screen, see figure 7.2-2.
6) The cover can now gently be released by pulling it upwards, see figure 7.2-4.
7) When reassembling the cabinet remember to place the screen cable on top of the computer box, see figure 7.2-5.

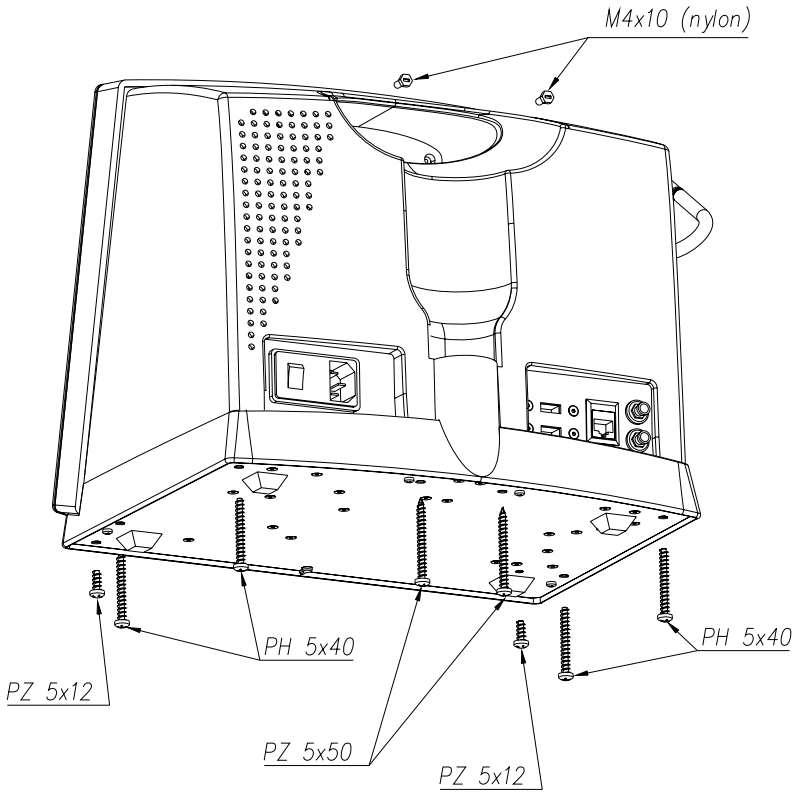


Figure 7.2-1 Disassembly cabinet – screws.

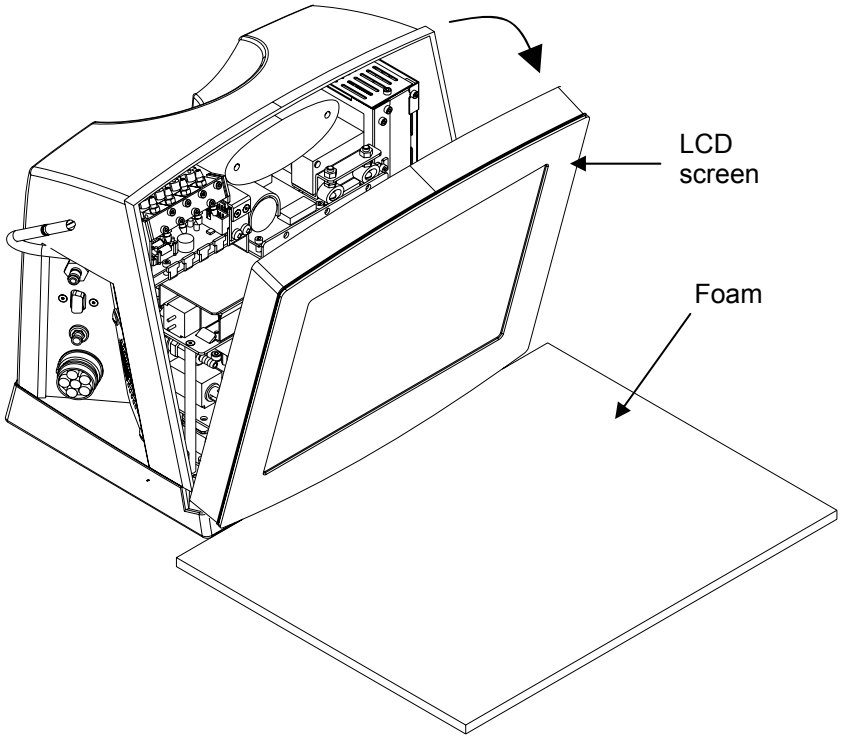


Figure 7.2-2 Disassembly cabinet – loosen LCD screen.

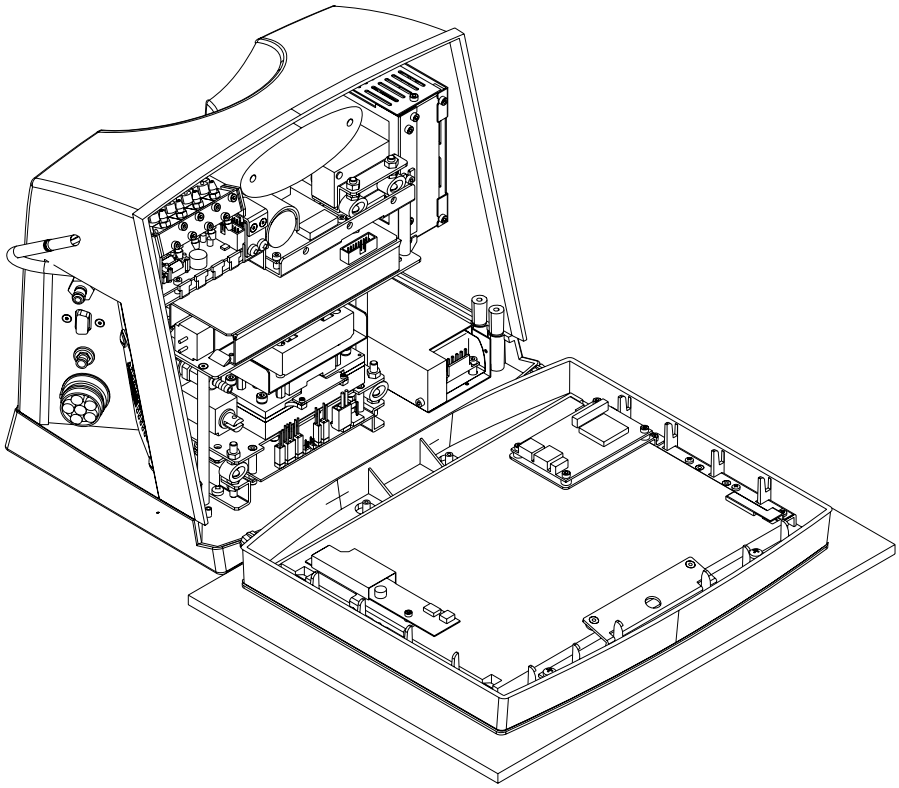


Figure 7.2-3 Disassembly cabinet – LCD screen on foam.

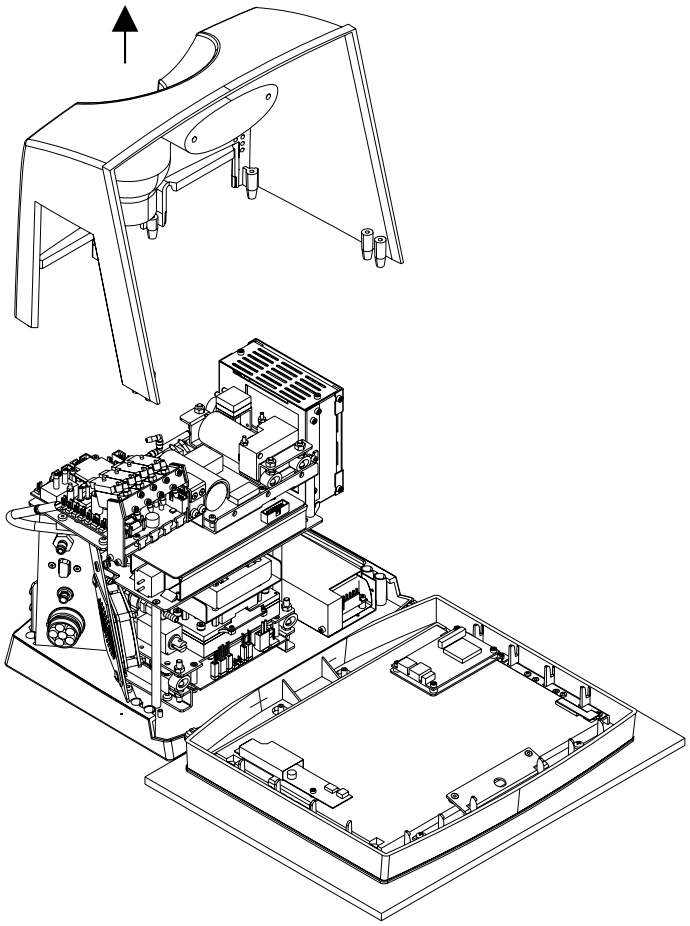


Figure 7.2-4 Disassembly cabinet – remove cover.

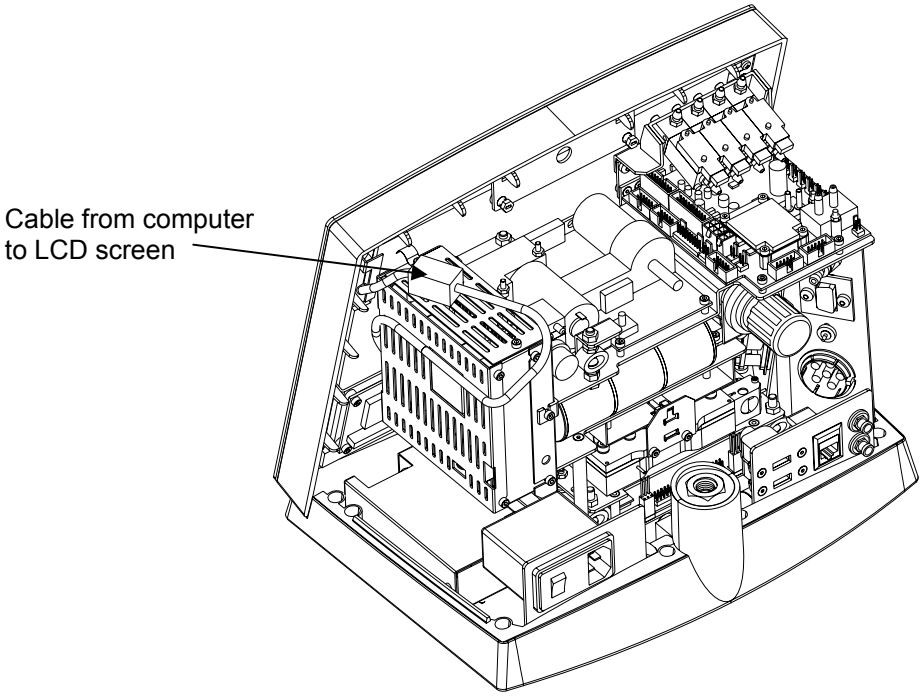


Figure 7.2-5 Assembly cabinet – location of cable between computer and screen.

The location of the different screws on the bottom plate is shown below:

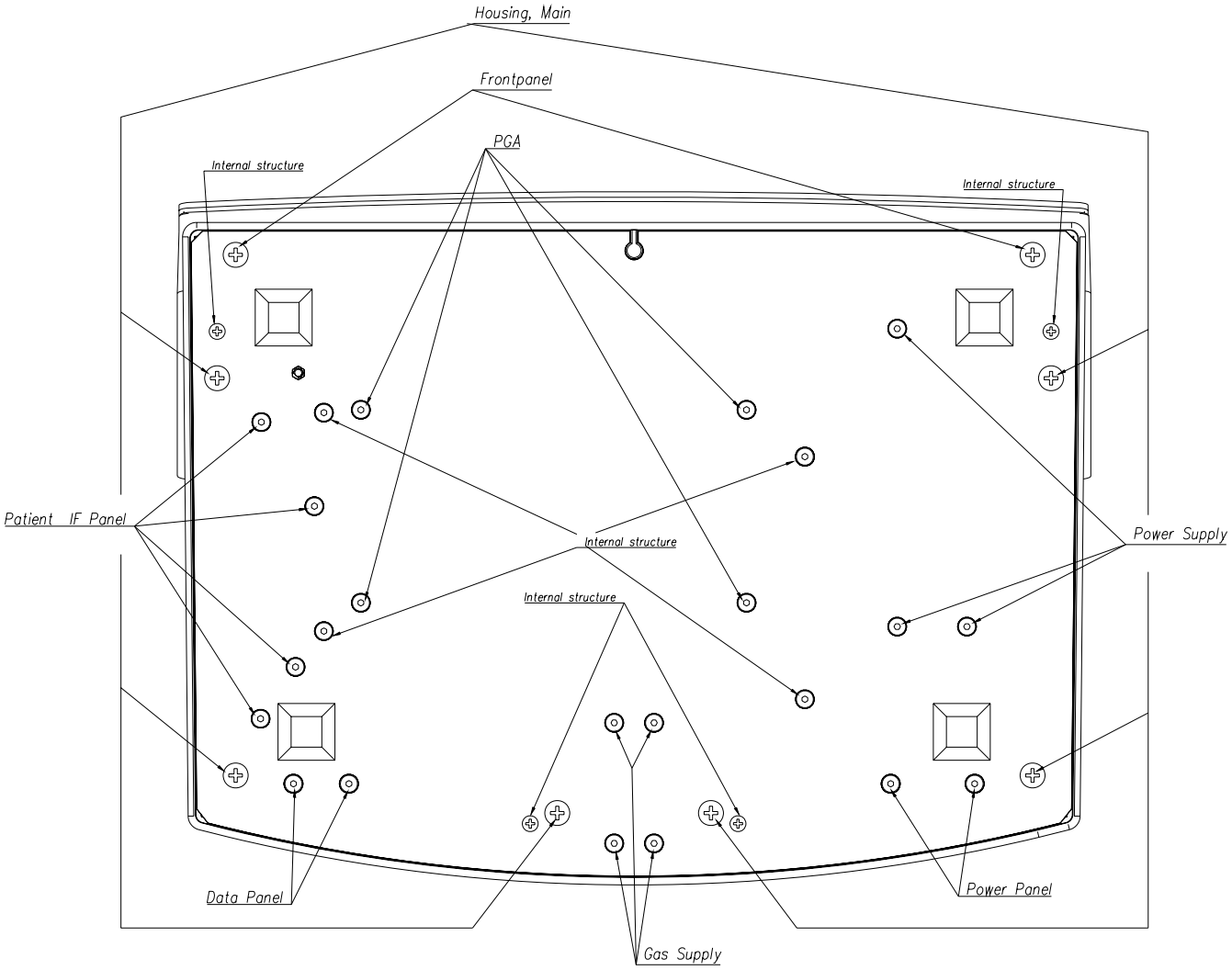


Figure 7.2-6 Location of screws on bottom plate.

7.3 PGA

The Photo Acoustic Analyser (PGA) is located on the bottom plate.

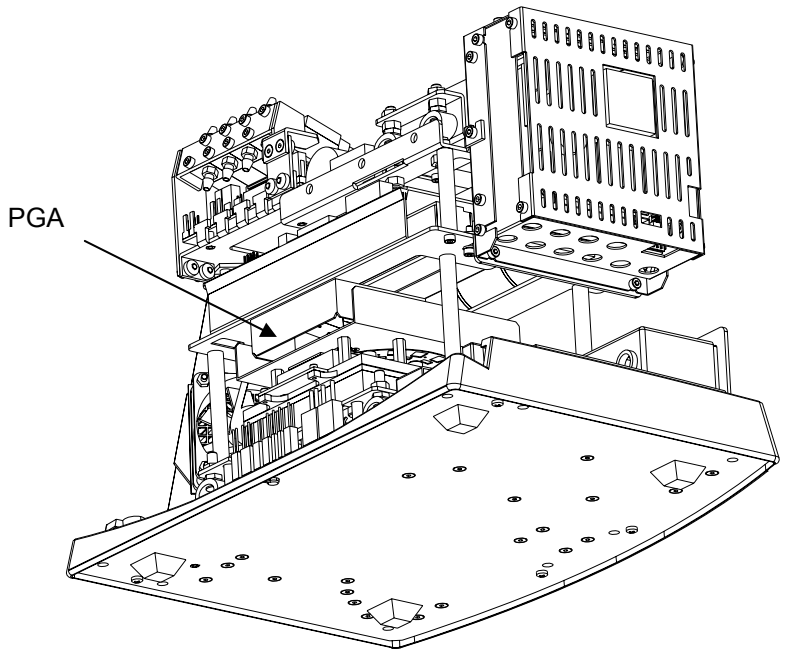


Figure 7.3-1 PGA location

When exchanging the PGA unit, start with disconnection all the external electronic and pneumatic connections:

1) Power
2) Serial communication line (to computer)
3) Digital I/O (to I/F Board)
4) Analogue line (to I/F Board)
5) Oxygen signal line
6) Power (to gas inlet pump)
7) Gas inlet (coming from oxygen sensor or directly from external connection if no oxygen sensor is installed)
8) Gas outlet (going to pulsation attenuator)

Find the four PGA mounting screws located on the bottom plate (M3, unbrako). A detailed plan on the bottom plate screws can be found on figure 7.2-6. Gently loosen the screws. Always exchange the mounting screws together with the PGA.

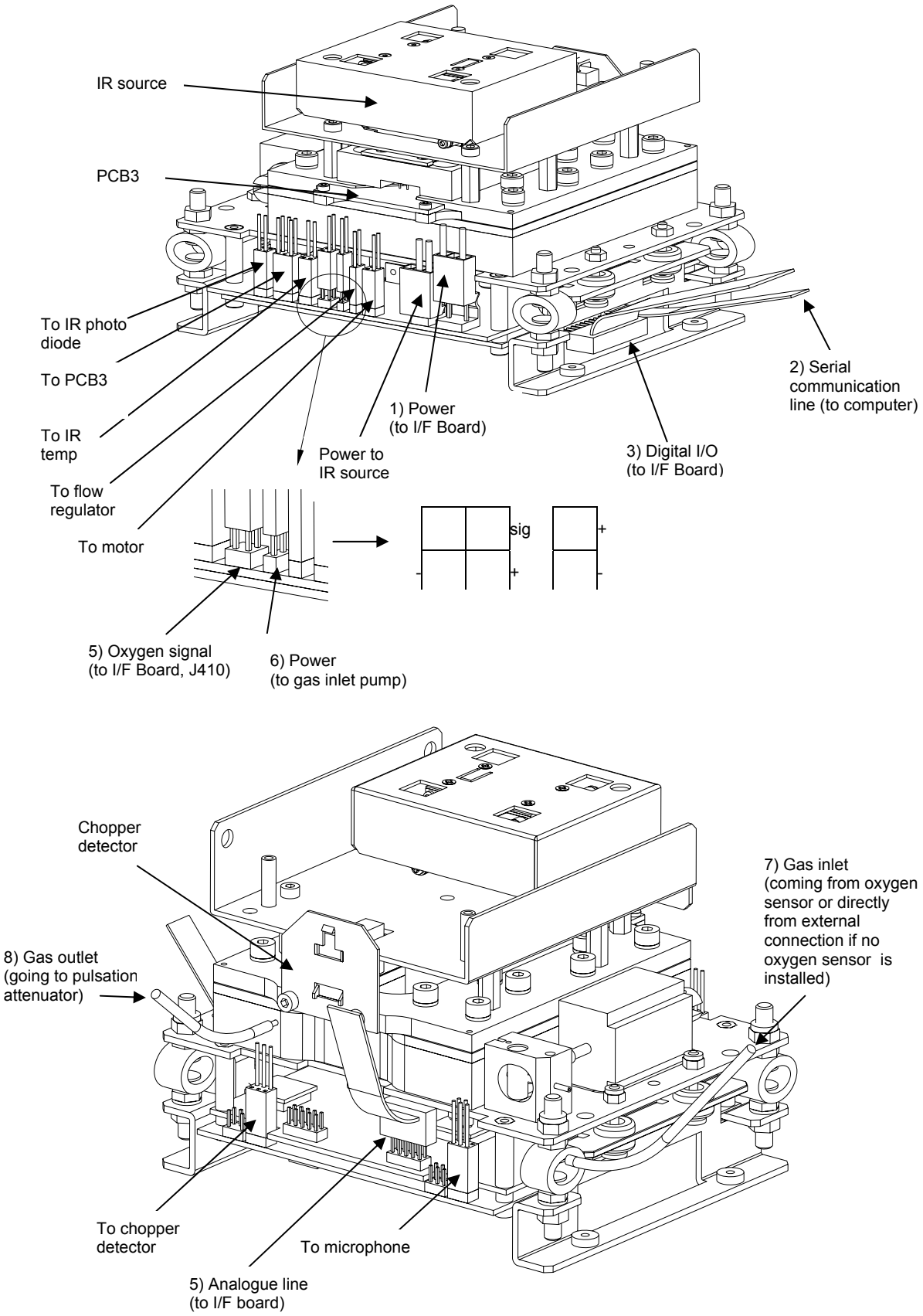


Figure 7.3-2 PGA exchange.

7.4 OXIGRAF

The oxygen sensor (Oxigraf) is located below the NIBP module and on top of the PGA.

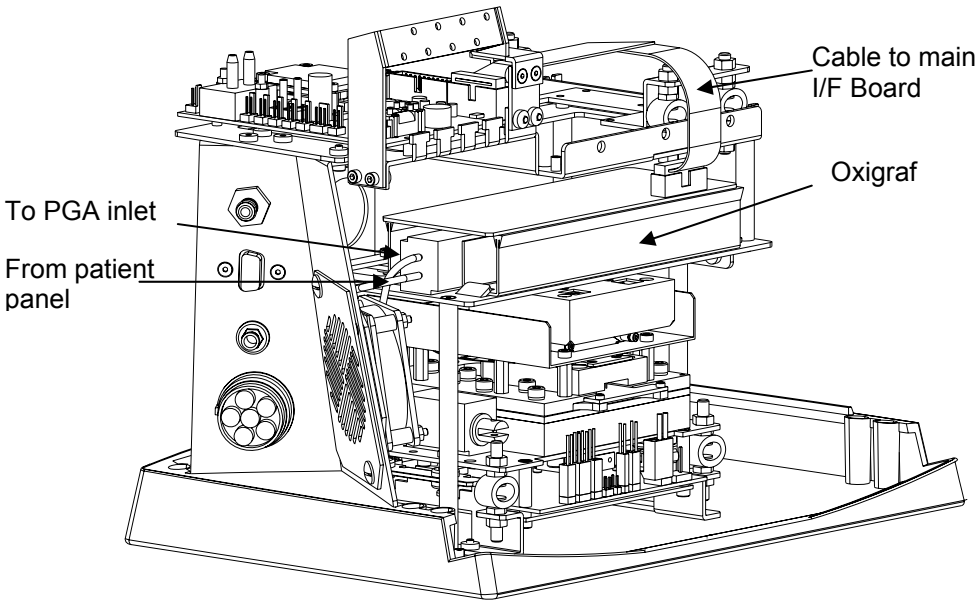


Figure 7.4-1 Oxygen sensor location.

When exchanging the oxygen sensor (Oxigraf), start with disconnection all the external electronic- and pneumatic connections:

1. Electrical interface to main I/F Board
2. Gas inlet (coming from the patient panel)
3. Gas outlet (going to PGA inlet)

Then unscrew the M3, unbrako, below the Oxigraf, see figure 7.4-3, and the Oxigraf can be loosened.

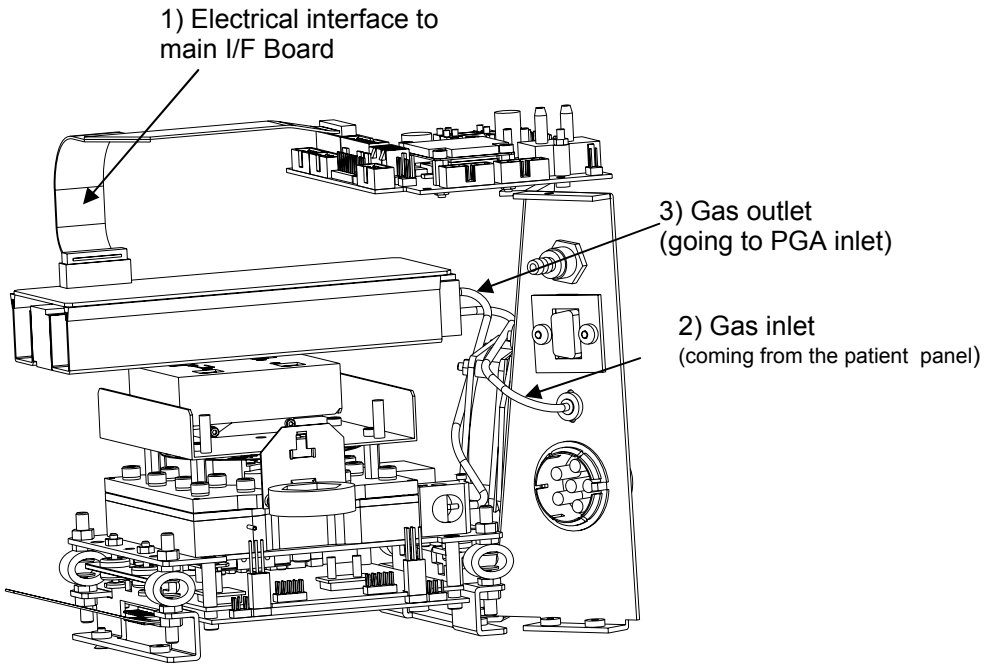


Figure 7.4-2 Oxygen sensor exchange.

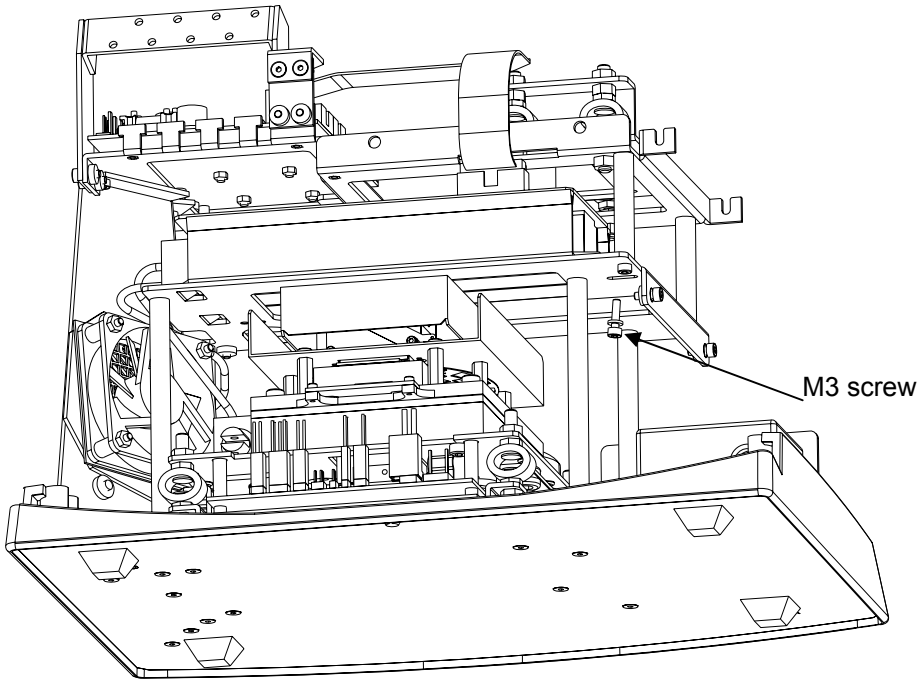


Figure 7.4-3 Oxygen sensor exchange (loosen screw).

7.5 VALVES

Innocor has a total of six solenoid valves. Four valves are mounted on the solenoid valve bracket over the I/F Board (Evac.,Air String, Pneu 2 & Pneu 1). The last two of smaller size are located on the I/F Board (Rebreathing & Zero Cal.).

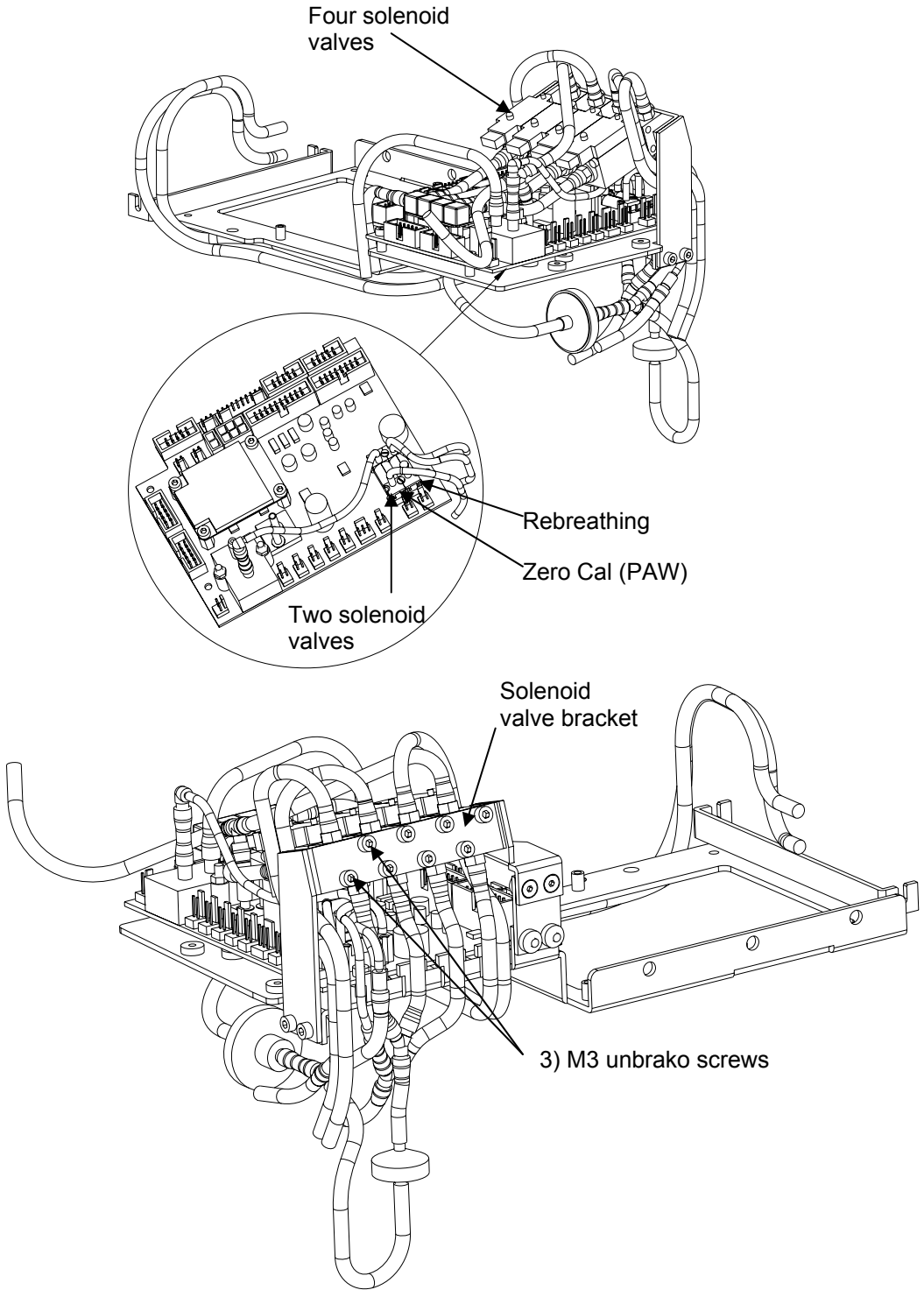


Figure 7.5-1 Solenoid valves exchange.

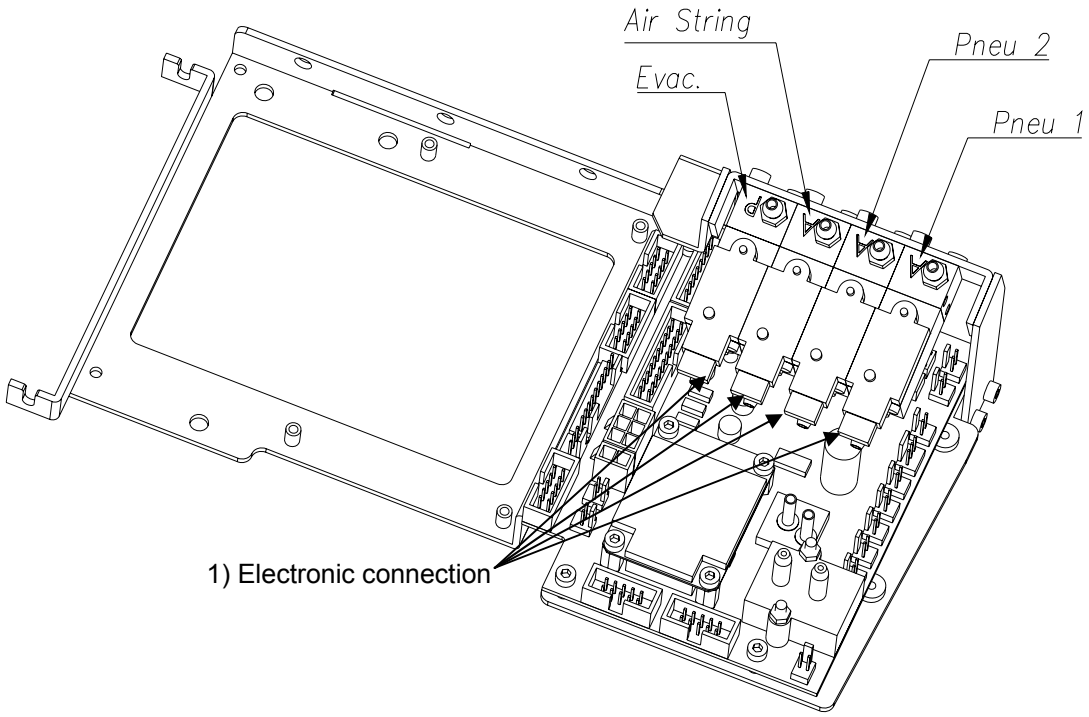


Figure 7.5-2 Definition of ports.

The solenoid valves used in Innocor are all of the so-called 3/2 type. This means that all valves have three ports and two positions. The three ports are named:

C: Common port
NC: Normally closed
R: Relief (Normally open)

In non-powered position the C and R ports are connected. In powered position the C and NC ports are connected.

For the four larger solenoid valves the port is defined as shown in the figure below. The P port is the NC port, and the A port is the C port. The end of the valve is the R port. Note, that during production the valve housing is rotated to get a better tubing layout.

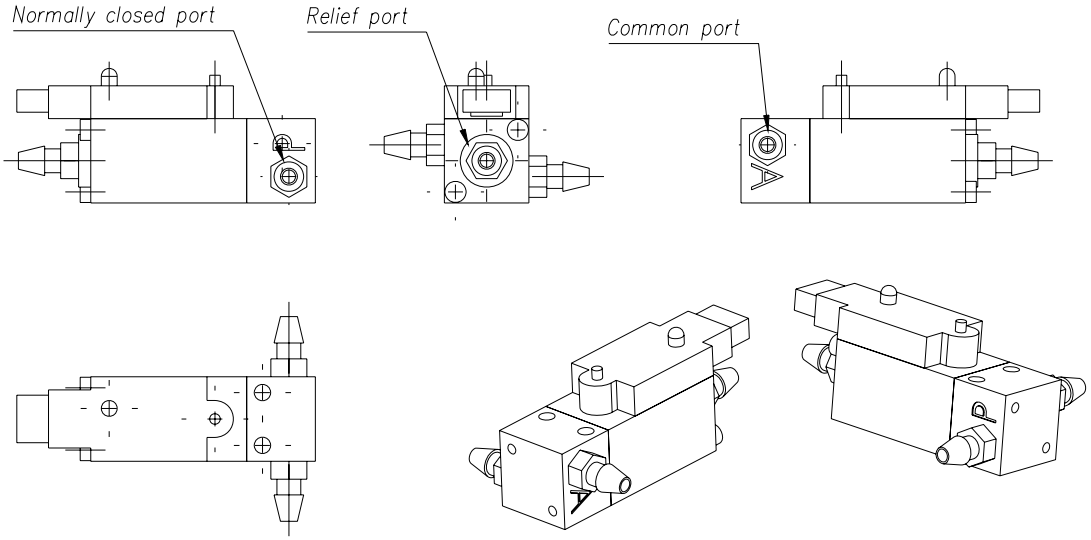


Figure 7.5–3. Layout of large solenoid valve.

For the two smaller solenoid valves located on the I/F Board the ports are defined as:

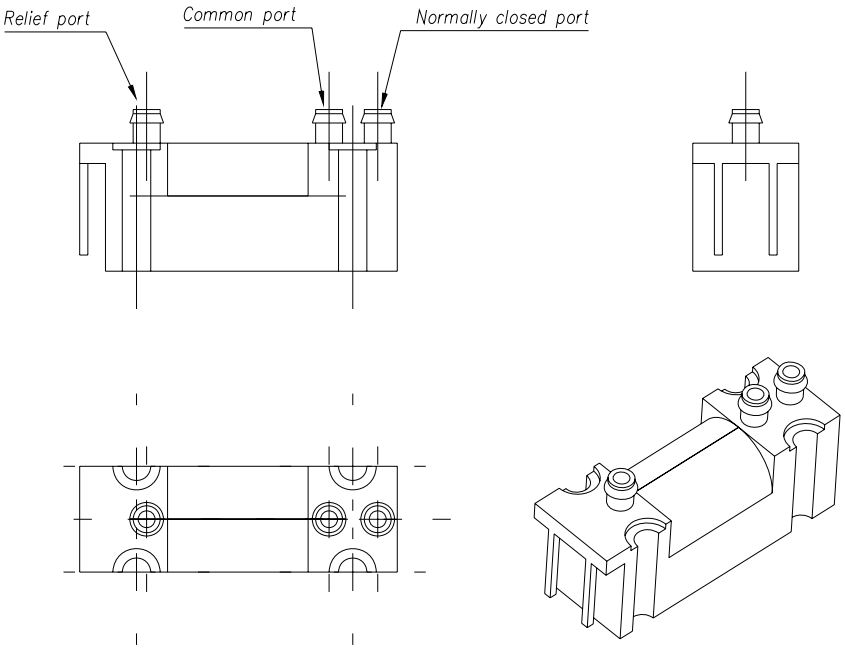


Figure 7.5–4. Layout of small solenoid valve.

When exchanging a valve perform the following steps:
Large valves:

1) Disconnect electronic connection.
2) Disconnect pneumatic connections (Note, the C, NC and R ports).
3) Unscrew the two M3x6 unbrako screws on the solenoid valve bracket, see figure 7.5–1.
4) Note, the right A & P port position, see figure 7.5–2, when replacing the valve.

Small valves:
1) Disconnect pneumatic connections (Note, the C, NC and R ports).
2) Unscrew the two small screws on the solenoid.

7.6 POWER SUPPLY

How to exchange the power supply

1) Disconnect mains supply.
2) Disconnect Output power connector.
3) Disconnect Output power connector.
4) Unscrew the two mounting screws located on the bottom plate (M3, unbrako). A detailed plan on the bottom plate screws can be found on figure 7.2-6. Gently loosen the screws. Always exchange the mounting screws together with the power supply.

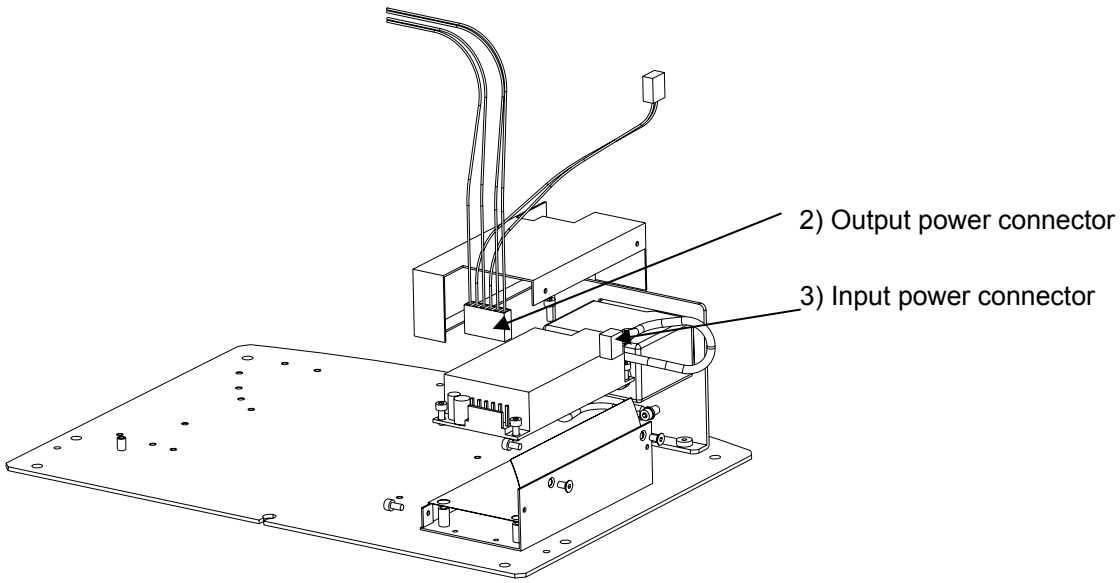


Figure 7.6-1 Location of power supply.

7.7 INLET PUMP

The gas inlet pump drives the sample flow for the PGA and the oxygen sensor (optional) through the pulsation attenuator.

How to exchange the inlet pump

1. First unscrew the three M5 nuts on the vibration dampers (see above).
2. Disconnect the power cord on the PGA, see figure 7.3-1, 6).
3. Then remove the flexible tubing on the gas inlet pump.
4. Unscrew the two small screws located on the bottom of the pump plate.

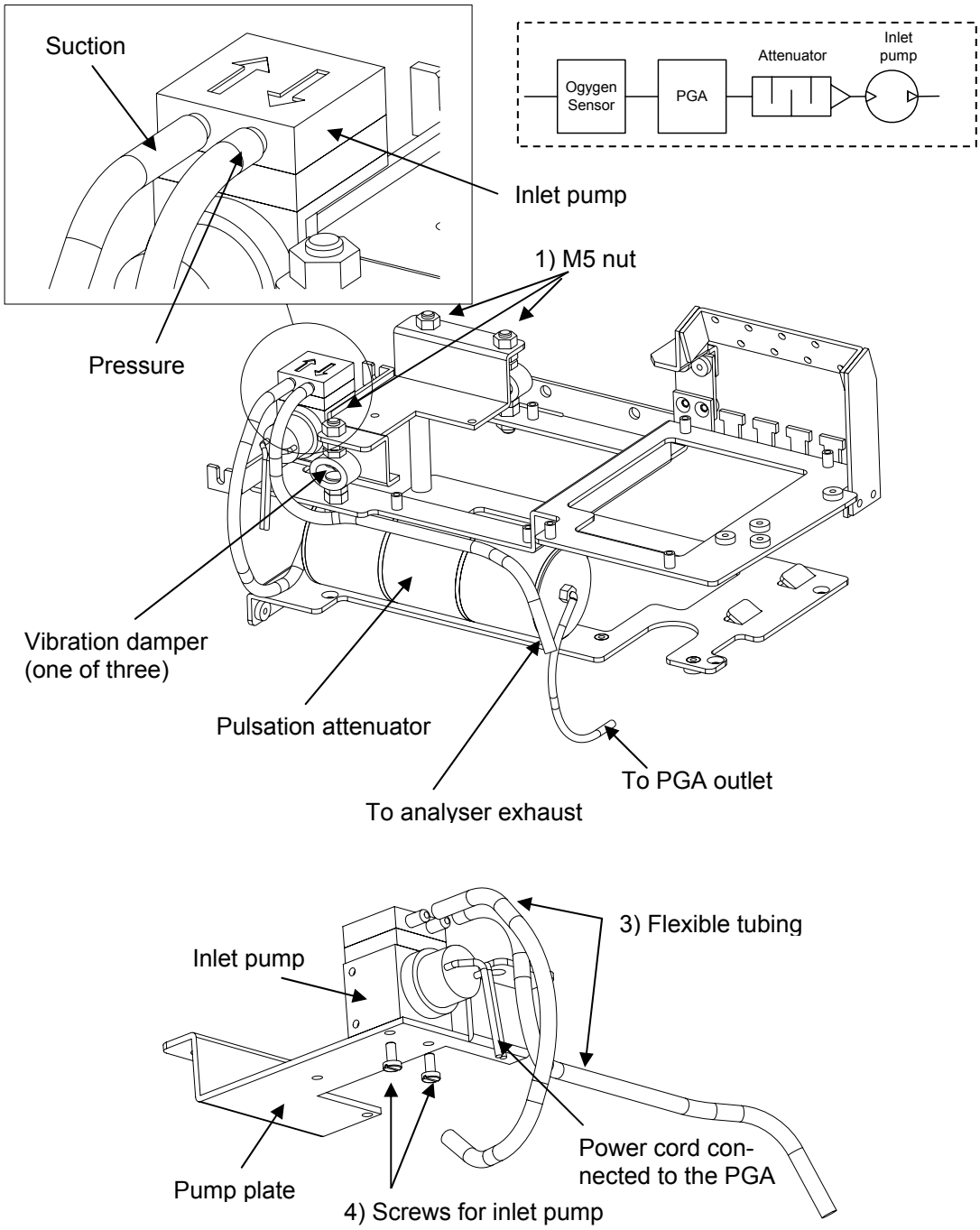


Figure 7.7–1 Gas inlet pump exchange.

7.8 AIR FILL / BAG EVACUATION PUMP

How to exchange the air filling- and evacuation pump

1. Disconnect the power on the I/F Board, see section 3.8.5.
2. Unscrew the three M5 nuts on the vibration dampers.
3. Remove the pump plate.
4. Remove (and replace if necessary) the flexible tubing.
5. Remove protective caps.
6. Unscrew the pump mounting screws and replace the pump.

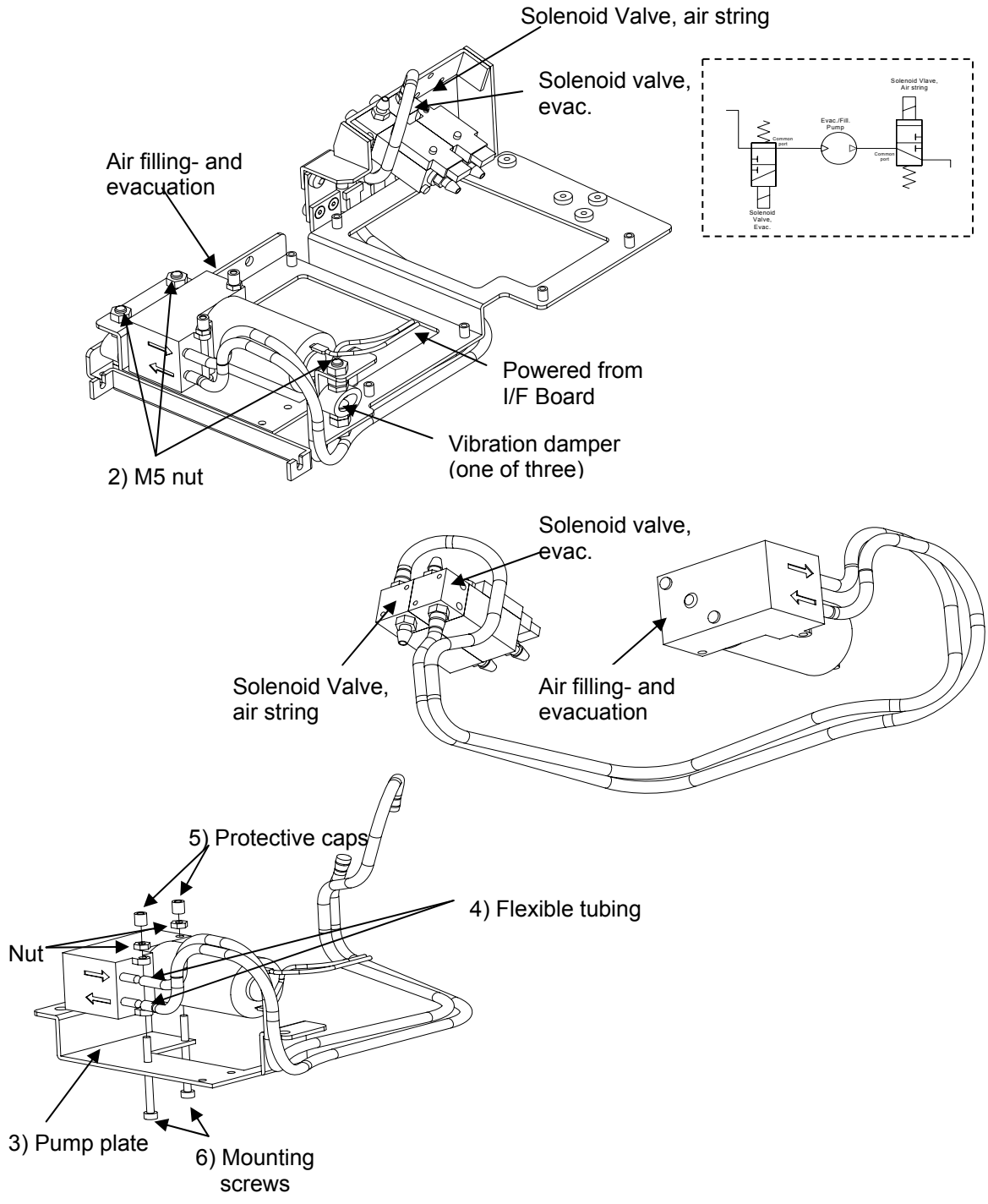
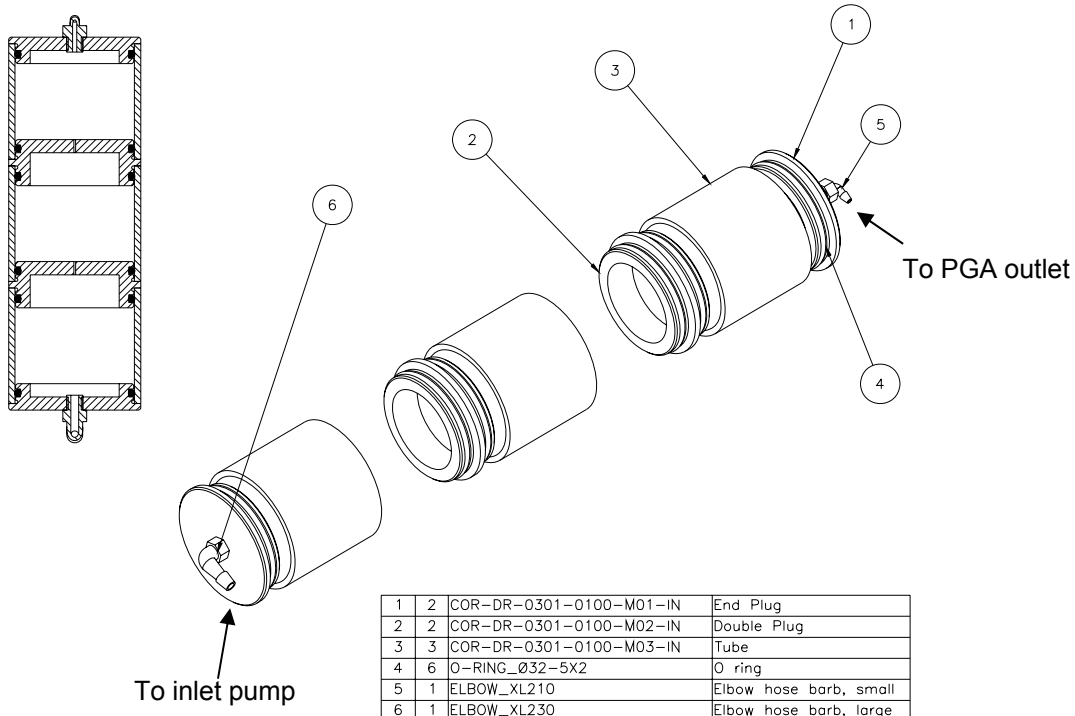


Figure 7.8–1 Air filling and evacuation pump exchange.

7.9 ACOUSTIC ATTENUATOR

How to exchange the acoustic attenuator

1. Disconnect tube to inlet pump (suction).
2. Disconnect tube to PGA outlet.
3. Cut strips around the attenuator.



Item	Qty	Part ID	Description
1	2	COR-DR-0301-0100-M01-IN	End Plug
2	2	COR-DR-0301-0100-M02-IN	Double Plug
3	3	COR-DR-0301-0100-M03-IN	Tube
4	6	O-RING_Ø32-5X2	O ring
5	1	ELBOW_XL210	Elbow hose barb, small
6	1	ELBOW_XL230	Elbow hose barb, large

Figure 7.9-1 Acoustic attenuator (damper) exchange.

7.10 COMPUTER

The single board computer is located in a box in the upper right corner.

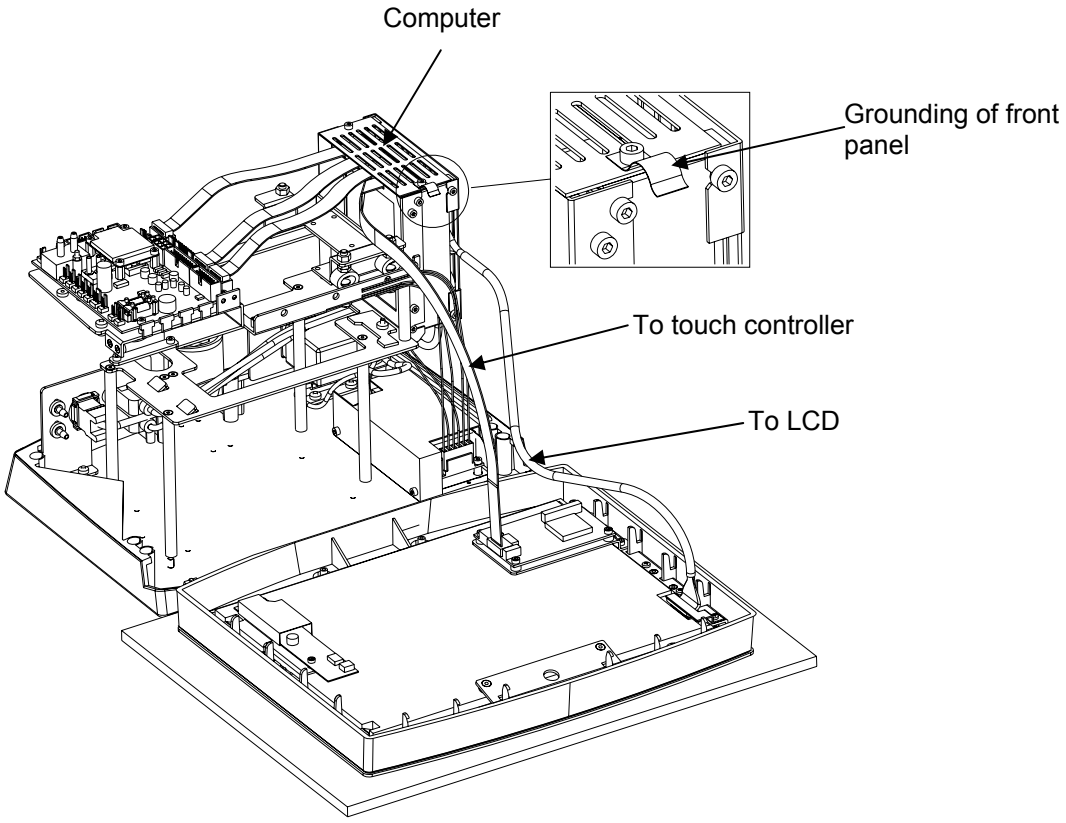


Figure 7.10-1 Computer location – seen from the front.

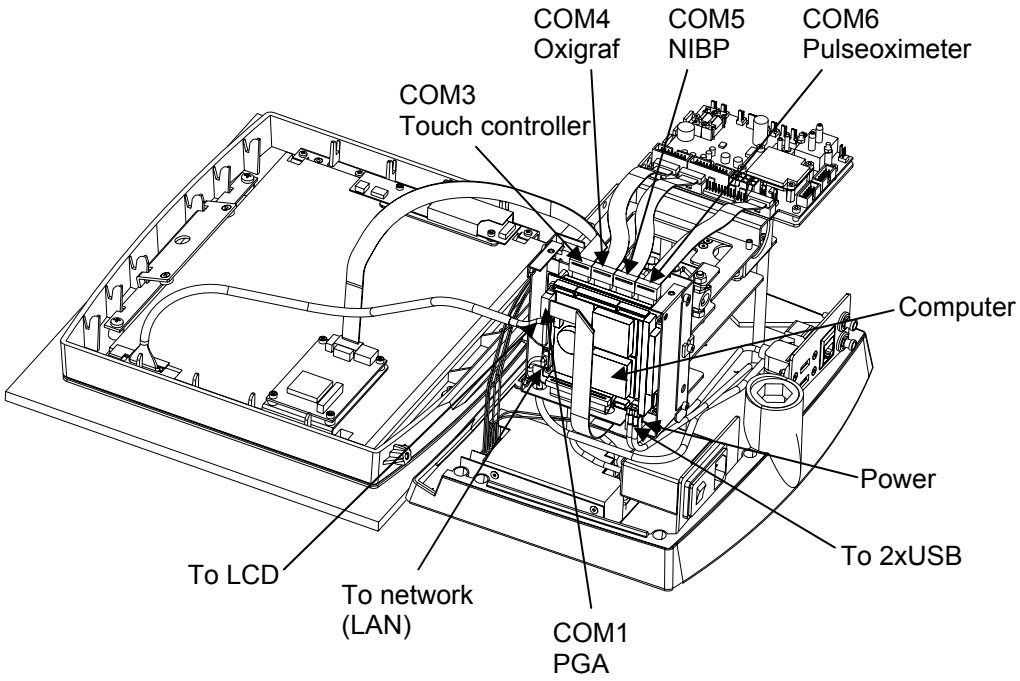


Figure 7.10-2 Computer location - seen from the right side.

In order to disconnect the computer perform the following steps:

1) Remove top panel by unscrewing two M3 screws.
2) Remove side panel by loosening four M3 screws.
3) Disconnect 4xserial cables.
4) Disconnect cable to LCD.
5) Disconnect network cable.
6) Disconnect 2xUSB cables.
7) Disconnect power cable.
8) Loosen 4 xM3 screws and disconnect computer.

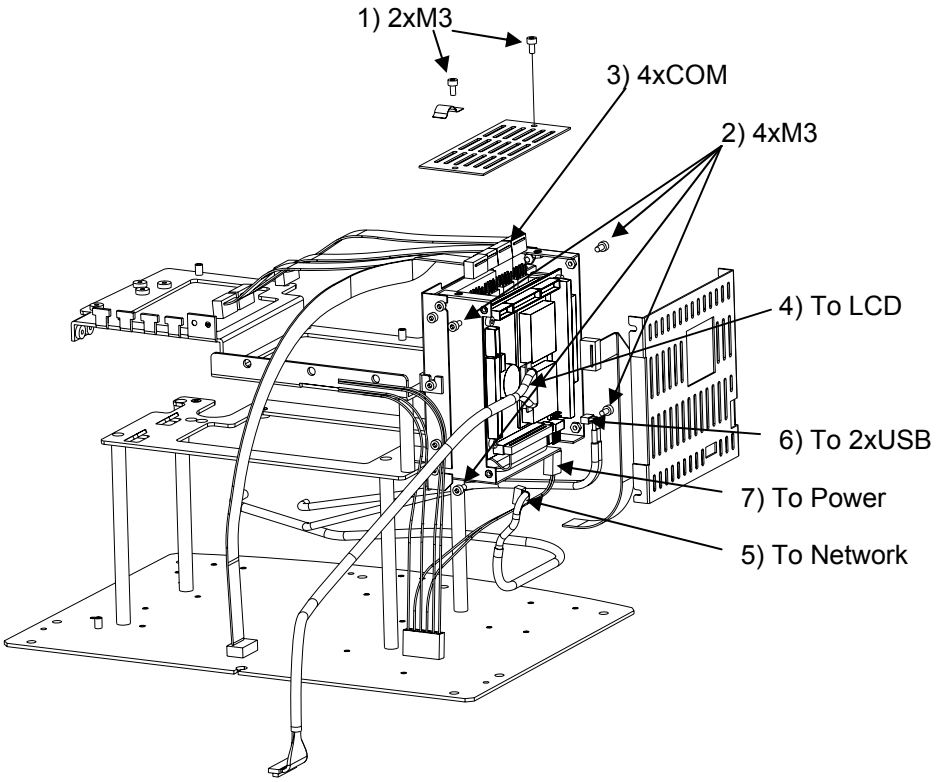


Figure 7.10-3 Disassembly of computer – step 1.

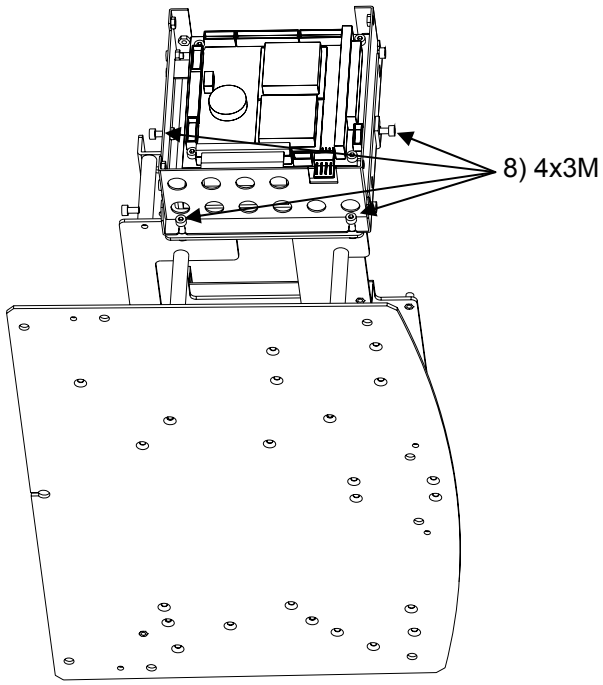


Figure 7.10-4 Disassembly of computer – step 2.

If a hard disk shall be replaced, follow the steps below:

1) Disconnect hard disk cable
2) Loosen two M3 screws
3) Remove four M3 screws

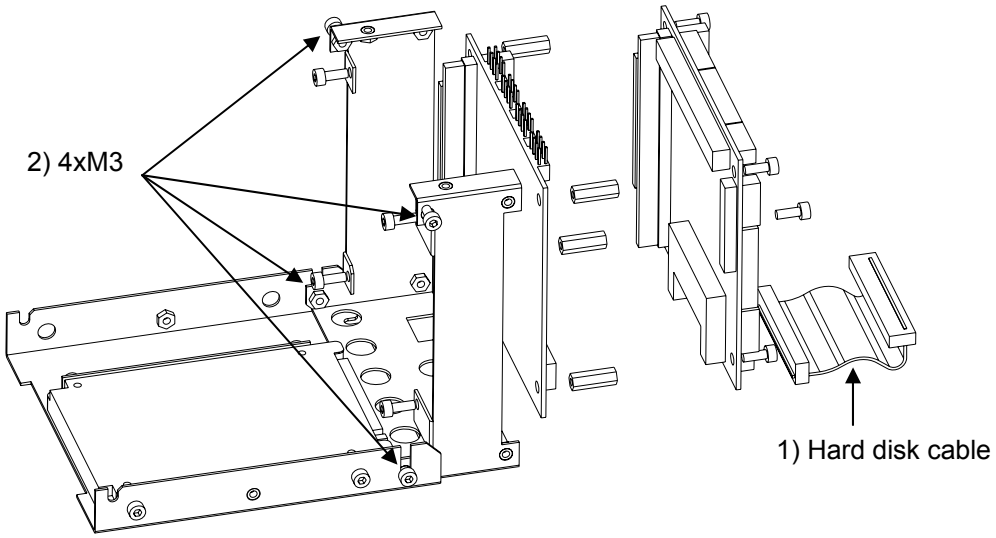


Figure 7.10-5 Exchange of hard disk – step 1

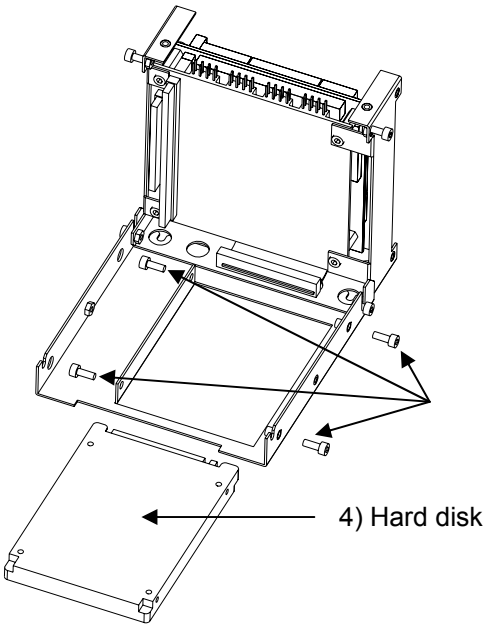


Figure 7.10-6 Exchange of hard disk – step 2

8 SPARE PARTS

For the locations of the spare parts see figures 8-1 to 8-12.

Item	Description	Part No.
1[1]	IF board, ver. 1 (for serial no 0226011 to 0314050)	SUB00024
	IF board, ver. 2 (for serial no 0320051 and newer)	SUB00032
2	Blood pressure electronic board (NIBP)	MPC00015
3	Evacuation / Filling pump	SUB00010
4	Oxygen analyser – Oxigraf – X2004.	OXI00001
5	Photo Acoustic Gas analyser (PGA) for measuring CO2, N2O and SF6.	SUB00016
6	Power Supply (100w)	SUB00034
7[2]	Touch screen controller (for serial no 0226011 to 0427100)	MPC00011
	Touch screen controller (for serial no 04xx101 and newer)	MPC00017
8	Fitting for blood pressure on patient panel (NIBP coupling, Male)	FIT00008
9	Flat cable between IF board and pulse oximeter connection on patient panel	CAB00015
10	Fitting for gas inlet on patient panel (Female Luer, 1/16” + Lock ring + Lock nut)	FIT00036
11	Fitting for RVU connection on patient panel (Six-tube SXF4202, Insert female)	FIT00009
12	Fan	SUB00009
13	Inverter controlling the back light	MPC00012
14	Gas sample pump	SUB00011
15	Solenoid valve for Evacuation, Airstring, Pneu 1 & 2 (+12V, 1.2W)	SOL00003
16	Pulse Oximeter electronic board	MPC00014
17	Low pressure regulator	SUB00028
18	Acoustic Attenuator	SUB00033
19	Fitting for in/out gas on data panel (Female Luer, 1/8”)	FIT00037
20	Data cable between single board computer and LAN connection on data panel	CAB00019
21	Data cable between single board computer and USB connection on data panel	CAB00020
22[3]	Gas manifold including high pressure regulator (for serial no 0226011 to 0335075)	SUB00027
	Gas manifold including high pressure regulator (for serial no 0345076 and newer)	SUB00035
23	Power Input Module including switch and panel	SUB00013
24[1]	Flat cable between IF board (ver. 2) and single board computer (COM 4,5&6)	CAB00025
	Flat cable between IF board (ver. 1) and single board computer (COM 4,5&6)	CAB00014 CAB00016 CAB00017
25	EMC finger	EMC00001
26	Power cable between power supply and IF board + single board computer	CAB00001
27	Flat serial cable between single board computer and touch screen controller	CAB00010
28	Power & data cable between single board computer and LCD display	CAB00007
29	LCD display including frame, but excluding Touch screen controller (MPC00011/MPC00017) and Inverter (MPC00012)	SUB00023
30	4x serial port – PCM-3641A	MPC00004
31	Single board computer - PCM-3350F, 300MHz	MPC00005
32	Flat power & data cable between single board computer and hard disk	CAB00009
33	Ferrit cable suppressor on LCD cable	FER00001
34	Power cable between IF board and PGA	CAB00002

Item	Description	Part No.
35	Flat cable (20 pins) between IF board and PGA for digital signals	CAB00023
36	Data cable between IF board and PGA transmitting oxygen signal	CAB00003
37	Tube, 1mmx1mm x 270mm, Viton	TUB00002-270
38	Tube, 1mmx1mm x 160mm, Viton	TUB00002-160
39[4]	Flat cable (10 pins) between IF board and PGA for analogue signals	CAB00010 / 18
40	Flat cable between IF board (ver. 2) and oxigraf	CAB00024
	Flat cable between IF board (ver. 1) and oxigraf (crossed)	CAB00013
41	One-way valve (Check valve)	VAL00001
42	Filter on gas input on low pressure side – Millex 25 mm	FIL00003
43	Solenoid valve for rebreathing and zero cal. (X-1-12-S-F)	SOL00002
	Solenoid valve for rebreathing and zero cal. (X-2-12-S-F) from serial no 0425092	SOL00004
44	M4x10 nylon	SCR00033
45	PZ 5x50	SCR00020
46	PZ 5x12	SCR00019
47	PZ 5x40	SCR00022
48	Harddisc	HDD00002
49	Power cable between IF Board and Touch Screen Controller (for serial no 0226011 to 0427100)	CAB00006
	Power cable between IF Board and Touch Screen Controller (for serial no 04xx101 and newer)	CAB00029
50	Ground connection between Bottom Plate and LCD Display	CAB00008
51	Power cable between IF Board and Inverter PCB	CAB00005
52	Serial cable from PGA to SBC	CAB00027
53	BBB sensor electronics	SUB00047
101	High Pressure Gas Supply Sensor	SUB00012
102	Relief Valve	VAL00003
103	Exhaust Port A/1	MEC00108
104	Fitting Manifold	SUB00036
105	Fitting, Y, 1/8"	FIT00017
106	Fitting, Barb 1/8-27 NPTx1/8"	FIT00034
107	Fitting, Barb 1/8-27 NPTx3/16"	FIT00035
108	Fitting, Luer Integral, 1/8"	FIT00028
109	Fitting, Y, 1/8"	FIT00017
110	Fitting, N, 1/8"-1/16"	FIT00015
111	Fitting, Y, 1/8"	FIT00017
112	Fitting, Barb, 1/8"	FIT00013
113	Fitting, T, 1/8"	FIT00016
114	Fitting, T, 1/8" - 1/16"	FIT00031
115	Fitting, L, 1/8"-1/16"	FIT00012
116	Fitting, Press-In Plug, 1/16"	FIT00014
117	Fitting, N, 1/8"-1/16"	FIT00015
118	Fitting, N, 1/8"-1/16"	FIT00015
119	Fitting, N, 1/8"-1/16"	FIT00015
120	Fitting, Y, 1/8"	FIT00017
121	PVC, natural, ID = 3mm, OD = 5mm, 20 mm	TUB00006-020
122	PVC, natural, ID = 3mm, OD = 5mm, 20 mm	TUB00006-020
123	PVC, natural, ID = 1/16”, OD = 1/8”, 100 mm	TUB00005-100
124	PVC, natural, ID = 1/16”, OD = 1/8”, 100 mm	TUB00005-100
125	PVC, natural, ID = 1/8”, OD = 1/4”, 80 mm	TUB00004-080
126	PVC, natural, ID = 1/8”, OD = 1/4”, 50 mm	TUB00004-050
127	PVC, natural, ID = 5mm, OD = 8mm, 160 mm	TUB00007-160

Item	Description	Part No.
128	PVC, natural, ID = 1/8”, OD = 1/4”, 60 mm	TUB00004-090
129	PVC, natural, ID = 1/8”, OD = 1/4”, 60 mm	TUB00004-100
130	PVC, natural, ID = 3mm, OD = 5mm, 25 mm	TUB00006-025
131	PVC, natural, ID = 3mm, OD = 5mm, 140 mm	TUB00006-140
132	PVC, natural, ID = 3mm, OD = 5mm, 30 mm	TUB00006-030
133	PVC, natural, ID = 3mm, OD = 5mm, 50 mm	TUB00006-050
134	PVC, natural, ID = 3mm, OD = 5mm, 20 mm	TUB00006-020
135	PVC, natural, ID = 1/16”, OD = 1/8”, 120 mm	TUB00005-120
136	PVC, natural, ID = 3mm, OD = 5mm, 350 mm	TUB00006-350
137	PVC, natural, ID = 3mm, OD = 5mm, 320 mm	TUB00006-320
138	PVC, natural, ID = 3mm, OD = 5mm, 170 mm	TUB00006-170
139	PVC, natural, ID = 3mm, OD = 5mm, 75 mm	TUB00006-075
140	Viton, ID = 1mm, OD = 3mm, 160 mm	TUB00002-160
141	PVC, natural, ID = 3mm, OD = 5mm, 130 mm	TUB00006-130
142	PVC, natural, ID = 3mm, OD = 5mm, 350 mm	TUB00006-350
143	PVC, natural, ID = 3mm, OD = 5mm, 240 mm	TUB00006-240
144	PVC, natural, ID = 3mm, OD = 5mm, 70 mm	TUB00006-070
145	PVC, natural, ID = 3mm, OD = 5mm, 60 mm	TUB00006-060
146	PVC, natural, ID = 3mm, OD = 5mm, 55 mm	TUB00006-055
147	PVC, natural, ID = 3mm, OD = 5mm, 55 mm	TUB00006-055
148	PVC, natural, ID = 3mm, OD = 5mm, 50 mm	TUB00006-050
149	PVC, natural, ID = 3mm, OD = 5mm, 530 mm	TUB00006-530
150	PVC, natural, ID = 3mm, OD = 5mm, 430 mm	TUB00006-430
151	PVC, natural, ID = 3mm, OD = 5mm, 20 mm	TUB00006-020
152	PVC, natural, ID = 3mm, OD = 5mm, 100 mm	TUB00006-100
153	PVC, natural, ID = 1/16”, OD = 1/8”, 70 mm	TUB00005-070
154	PVC, natural, ID = 3mm, OD = 5mm, 100 mm	TUB00006-100
155	PVC, natural, ID = 3mm, OD = 5mm, 20 mm	TUB00006-020
	PVC, natural, ID = 3mm, OD = 5mm, 100 mm, from serial no 0425092	TUB00006-100
156	PVC, natural, ID = 1/16”, OD = 1/8”, 200 mm	TUB00005-200
	PVC, natural, ID = 1/16”, OD = 1/8”, 160 mm, from serial no 0425092	TUB00005-160
157	PVC, natural, ID = 3mm, OD = 5mm, 270 mm	TUB00006-270
158	PVC, natural, ID = 3mm, OD = 5mm, 200 mm	TUB00006-200
	PVC, natural, ID = 3mm, OD = 5mm, 160 mm, from serial no 0425092	TUB00006-160
159	PVC, natural, ID = 1/16”, OD = 1/8”, 10 mm	TUB00005-100
160	PVC, natural, ID = 1/16”, OD = 1/8”, 5 mm	TUB00005-005
161	PVC, natural, ID = 1/16”, OD = 1/8”, 500 mm	TUB00005-500
162[5]	PVC, natural, ID = 1/16”, OD = 1/8”, 120 mm	TUB00005-120
163	PVC, natural, ID = 1/16”, OD = 1/8”, 150 mm	TUB00005-150
164	PVC, natural, ID = 1/16”, OD = 1/8”, 300 mm	TUB00005-300

Notes:

1. The SUB00024 (IF board, ver. 1) is replaced by SUB00032, CAB00024, CAB00025 and 3 x CAB00026.
2. MPC0011 can be replaced by MPC00017 and CAB00029
3. Gas manifold SUB00027 cannot be replaced by SUB00035
4. Without BbB: CAB00018.
   With BbB: CAB00018 between PGA and BbB sensor electronics, CAB00010 between I/F board and BbB sensor electronics (same cable but different length).
5. Factory adjusted between 120 and 100 mm in order to balance the 2 pressure lines

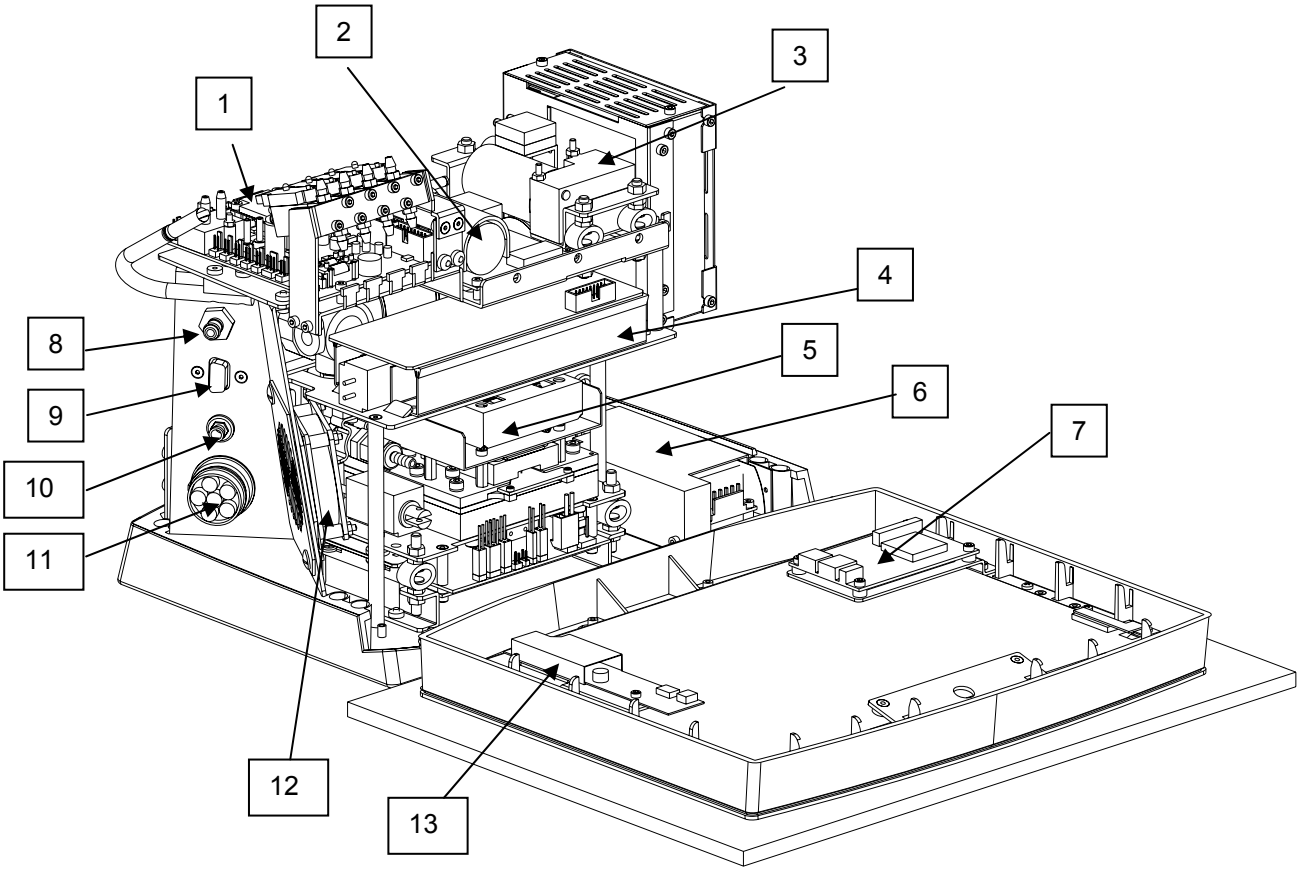
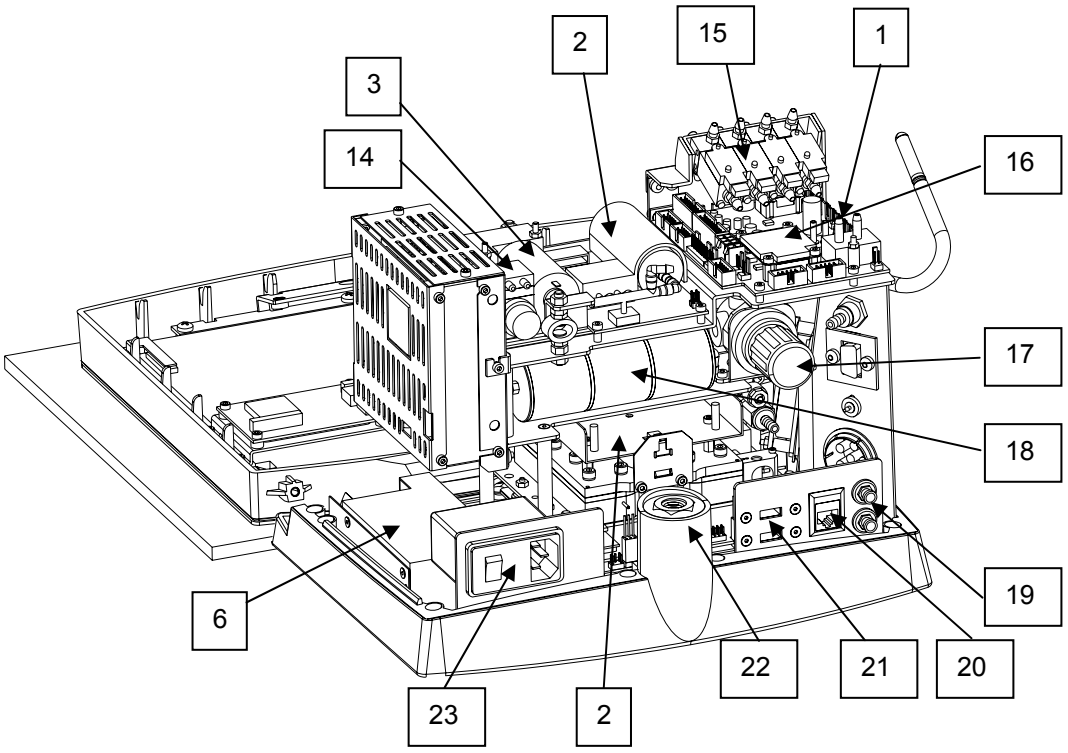


Figure 8-1



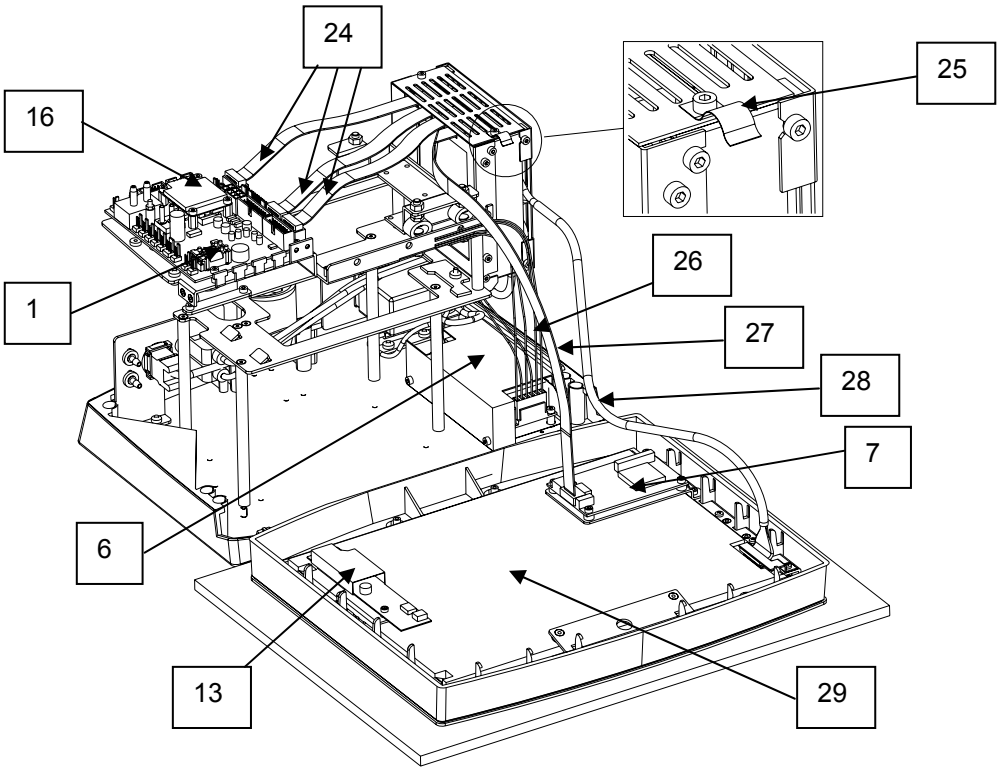


Figure 8-2
Figure 8-3

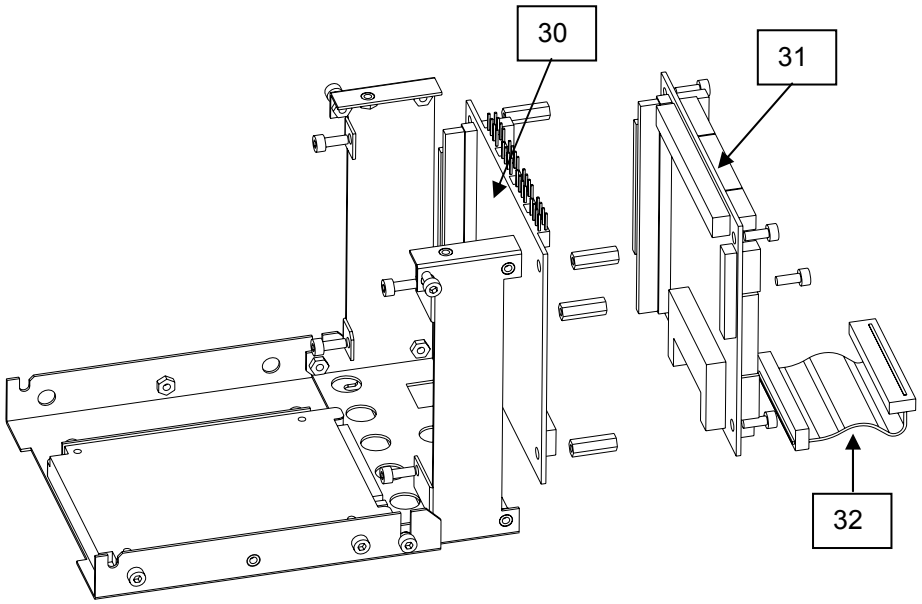


Figure 8-4

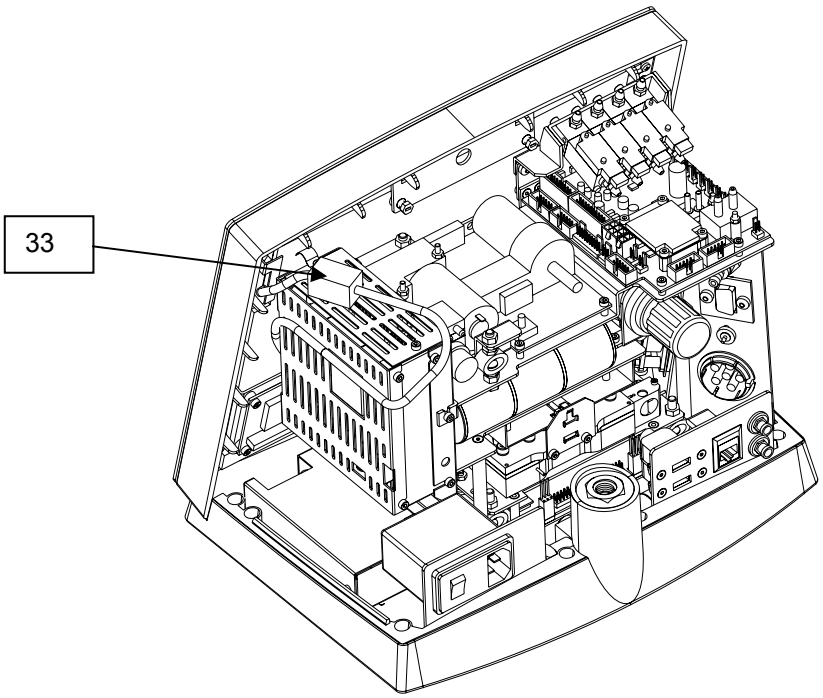


Figure 8-5

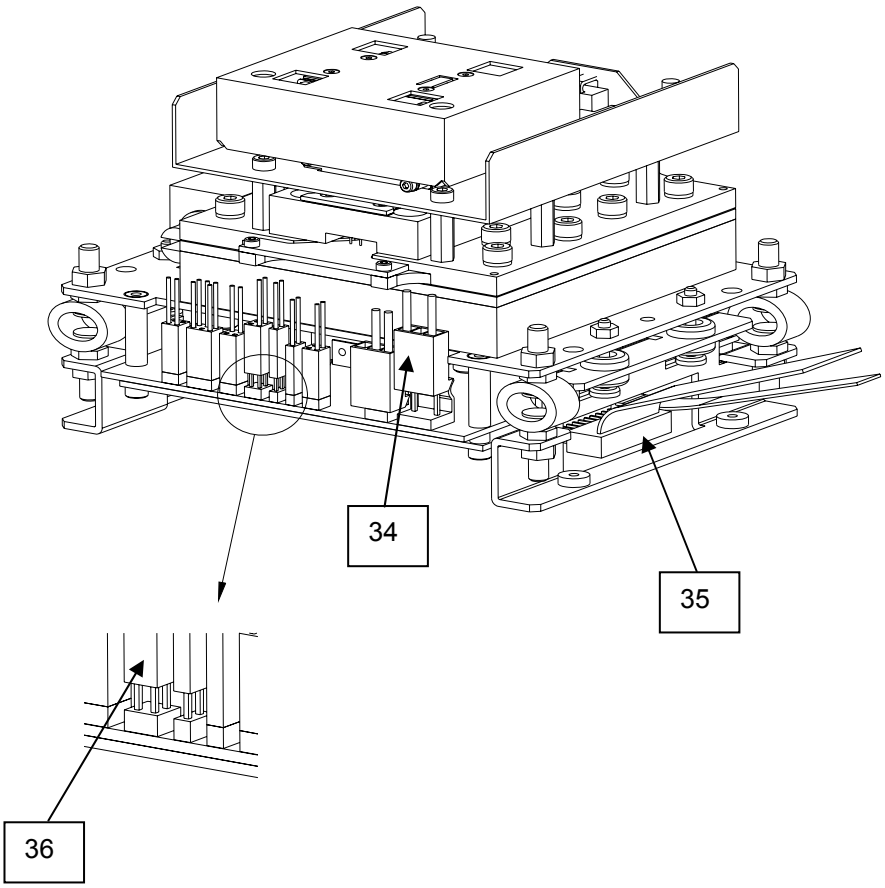


Figure 8-6

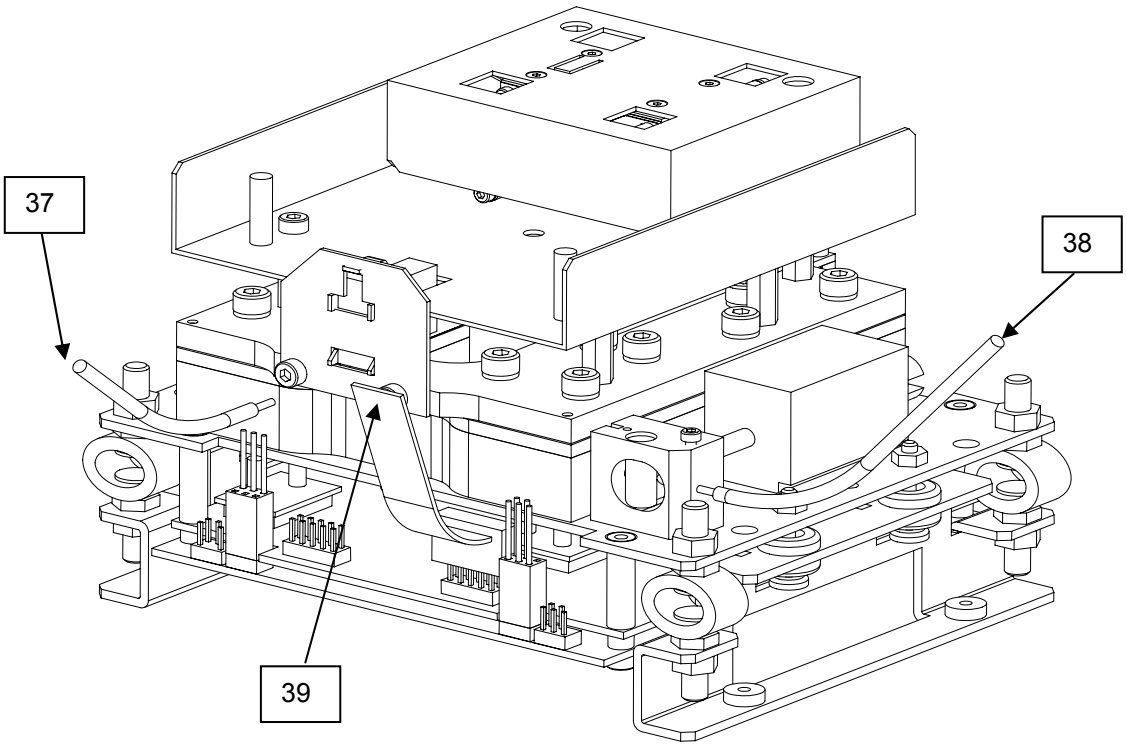


Figure 8-7

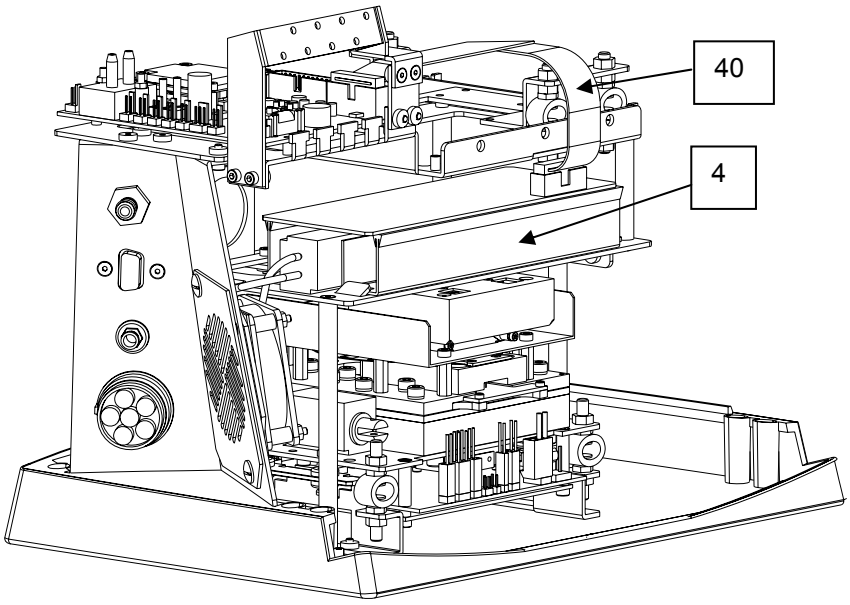


Figure 8-8

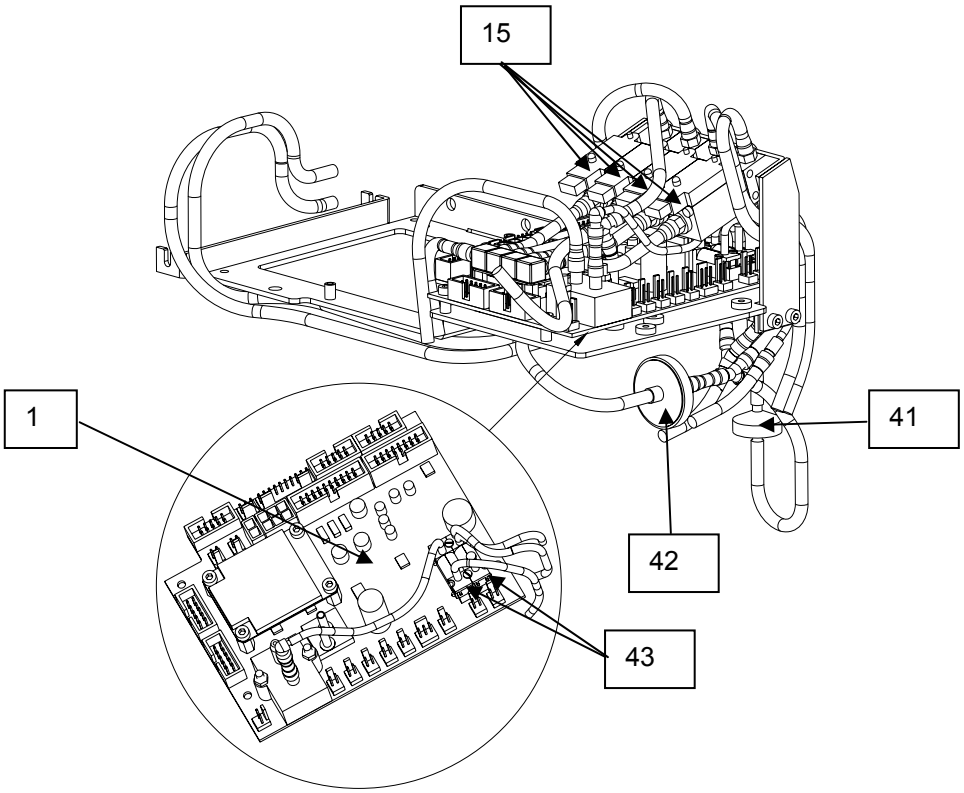


Figure 8-9

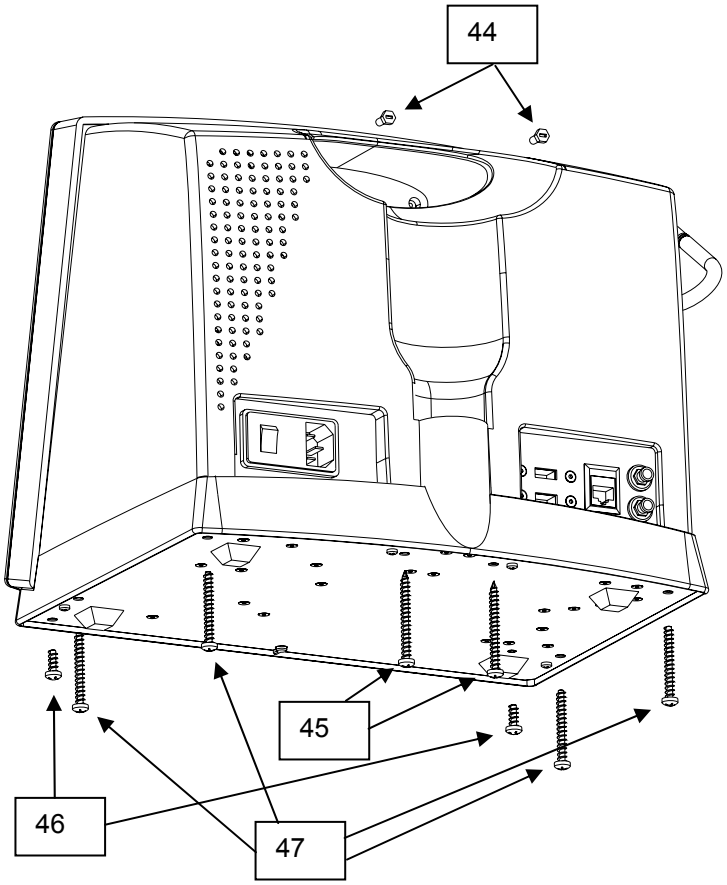


Figure 8-10

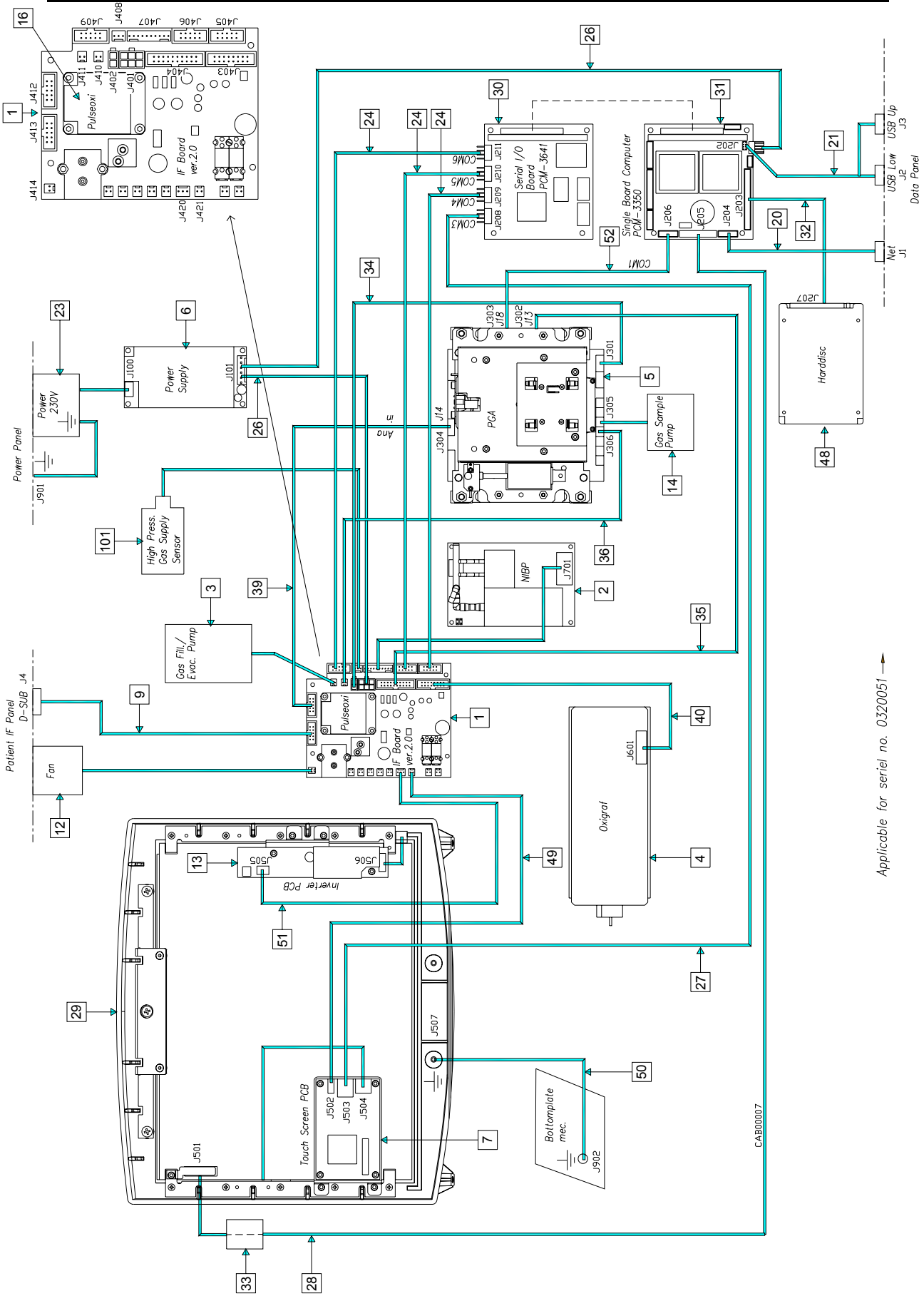


Figure 8-11 Wiring diagram without Breath-by-Breath

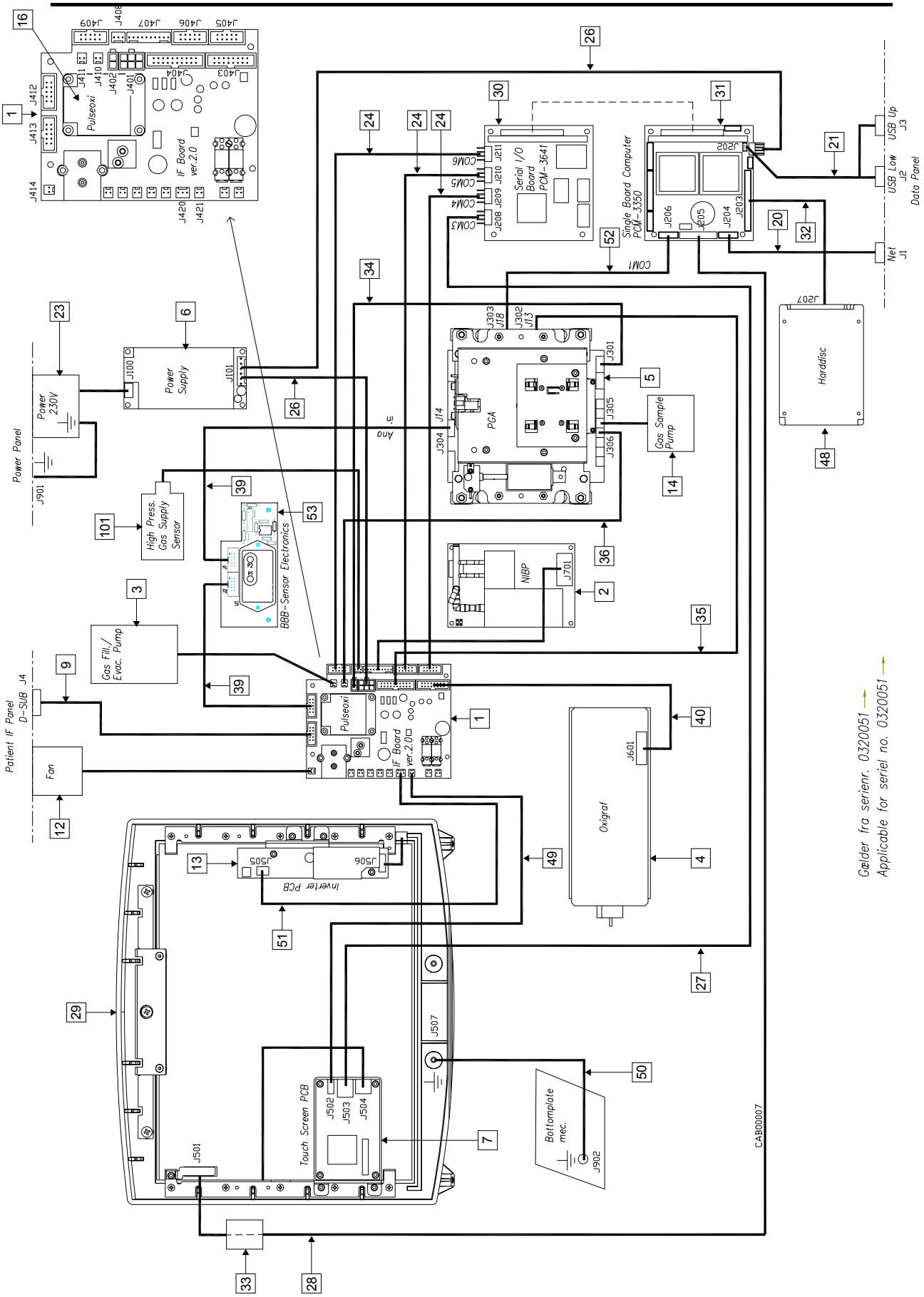


Figure 8-12 Wiring diagram with Breath-by-Breath

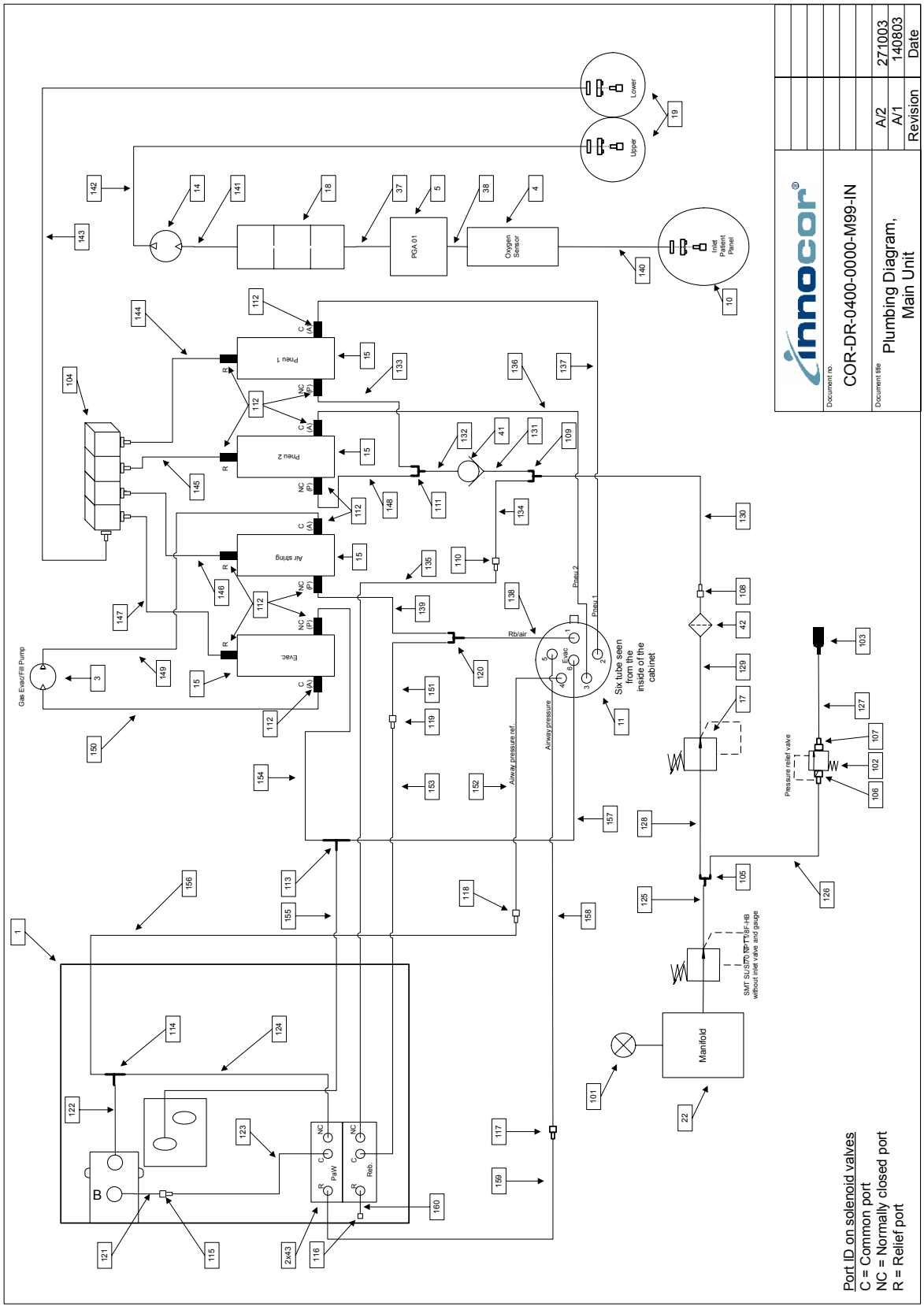


Figure 8-13 Plumbing diagram without Breath-by-Breath

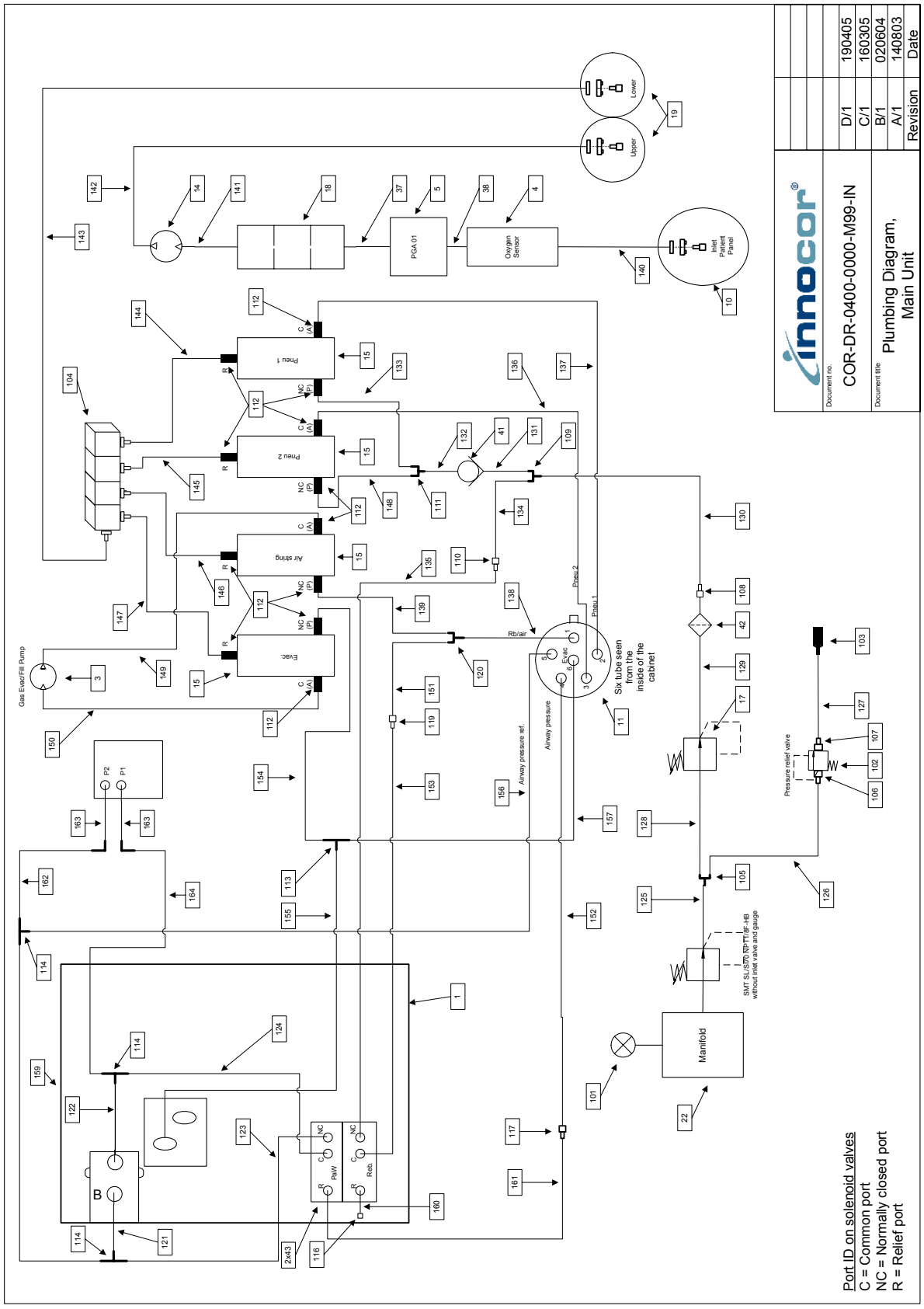


Figure 8-14 Plumbing diagram with Breath-by-Breath